Recommendations on NEW DRUGS from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice

In alphabetical order

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.12.12 *SMC Report No. 811/12*	5-aminolaevulinic acid (as hydrochloride), 78mg/g, gel (Ameluz®) *Biofrontera Bioscience GmbH* *Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).*	Accepted for use: 5-aminolaevulinic acid (as hydrochloride) (Ameluz®) is accepted for use within NHS Scotland for the treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2). In a multi-centre, randomised, observer-blind, controlled phase III study, 5-aminolaevulinic acid gel met pre-specified non-inferiority criteria compared with an alternative topical agent in terms of complete clearance of actinic keratosis lesions, 12 weeks after the last of up to two sessions of photodynamic therapy. The treatment difference was sufficient to demonstrate superiority over the alternative topical agent.	**Included** on the LJF as a prescribing note, Specialist Use only, for the indication in question. FC October 2013
09.05.05 *SMC Report No. 174/05* PRODUCT UPDATE (abbreviated submission)	abacavir (Ziagen®) *GlaxoSmithKline* *HIV.*	Accepted for use: abacavir tablets 300mg are accepted for use in a once-daily dosing regimen in NHS Scotland for treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults and adolescents over 12 years, in combination with other antiretroviral medicinal products.	Added to the Additional List, for Specialist Use only. FC June 2005
09.05.05 *SMC Report No. 175/05* PRODUCT UPDATE (abbreviated submission)	abacavir/lamivudine combination (Kivexa®) *GlaxoSmithKline* *HIV.*	Accepted for use: tablets delivering a fixed dose combination of abacavir 600mg and lamivudine 300mg are accepted for use in NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults and adolescents over 12 years, in combination with other antiretroviral medicinal products. Both products are nucleoside reverse transcriptase inhibitors. In patients for whom this combination is appropriate, it offers a single tablet at a lower cost per dose compared with the individual components.	Added to the Additional List, for Specialist Use only. FC June 2005
August 2009 *NICE MTA 195* *Supersedes SMC Report No. 400/07*	abatacept, 250mg powder for concentrate for solution (Orencia®) *Bristol Myers Squibb Pharmaceuticals Ltd* *In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease modifying anti rheumatic drugs including at least one tumour necrosis factor (TNF) inhibitor.*	abatacept (Orencia®) in combination with methotrexate is recommended as a treatment option only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDS, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.	Added to the Additional List, for Specialist Use only. FC March 2011

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07.11.11 SMC Report No. 618/10 PRODUCT UPDATE (abbreviated submission)	abatacept (Orencia®) 250mg powder for concentrate for solution for injection *Bristol-Myers Squibb Pharmaceuticals Ltd* *In combination with methotrexate, abatacept is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other disease modifying antirheumatic drugs (DMARDs) including at least one tumour necrosis factor (TNF) inhibitor.*	Restricted use: abatacept (Orencia®) powder for solution for injection is accepted for restricted use within NHS Scotland in combination with methotrexate, abatacept is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other disease modifying antirheumatic drugs (DMARDs) including at least one tumour necrosis factor (TNF) inhibitor. It has not been studied in children under 6 years old. It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Abatacept is an anti-rheumatic agent that prevents T-lymphocyte activation. Abatacept in combination with methotrexate has been accepted for restricted use in adults with severe active rheumatoid arthritis in line with the recommendations of the NICE Multiple Technology Appraisal no 195. NHS Quality Improvement Scotland advised that these recommendations were valid for NHS Scotland.	Added to the Additional List, Specialist Use only. FC March 2012
08.04.13 *SMC Reprot No. 719/11* RESUBMISSION Patient Access Scheme	abatacept 250mg powder for concentrate for solution for infusion (Orencia®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.*	Restricted use: abatacept (Orencia®) is accepted for restricted use within NHS Scotland in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor. SMC restriction: abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart. In combination with methotrexate, abatacept reduced the progression of joint damage and improved physical function more than placebo in patients with moderate to severe rheumatoid arthritis who responded inadequately to previous therapy with methotrexate alone. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abatacept. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC July 2013

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12.08.13 SMC Report No. 888/13 PRODUCT UPDATE (abbreviated submission) Patient Access Scheme	abatacept 125mg/mL solution for subcutaneous injection in a pre-filled syringe (Orencia®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.*	Restricted use: abatacept 125mg/mL solution for subcutaneous injection (Orencia®) is accepted for restricted use within NHS Scotland in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor. SMC restriction: abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart. SMC has previously accepted abatacept 250mg powder for concentrate for solution for infusion (Orencia®) for restricted use in NHS Scotland for this indication. Abatacept 125mg/mL subcutaneous injection (Orencia®) is more expensive on a mg-for-mg basis than abatacept 250mg powder for concentrate for solution for infusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abatacept. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, Specialist Use only for the indication in question. FC August 2013
13.08.12 *SMC Report No. 764/12* RESUBMISSION Patient Access Scheme	abiraterone acetate 250mg tablets (Zytiga®) *Janssen-Cilag Ltd* *With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.*	Restricted use: abiraterone acetate (Zytiga®) is accepted for restricted use within NHS Scotland with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. SMC restriction: abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen. Abiraterone plus prednisone was associated with significantly improved overall survival compared with placebo plus prednisone in patients with mCRPC previously treated with docetaxel. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	**Included** on the Additional List, Specialist Use only for the indication in question. FC October 2012
13.05.13 *SMC Report No. 873/13* NON SUBMISSION	abiraterone (Zytiga®) 250 mg tablets *Janssen-Cilag Ltd* *Indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.*	NOT RECOMMENDED: abiraterone (Zytiga®) is not recommended for use within NHS Scotland with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. The sponsor company plan to make a submission to SMC in December 2013.	NOT RECOMMENDED
12.11.12 *SMC Report No. 810/12*	aclidinium 322 micrograms inhalation powder (Eklira Genuair®) *Almirall S.A.* *As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).*	Accepted for use: aclidinium (Eklira Genuair®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). In two phase III studies, aclidinium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [FEV_1]) after 12 weeks and 24 weeks.	**Included** on the LJF as first choice drug for the indication in question. FC January 2013

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08.12.03 *SMC Report No. 81/03*	adalimumab (Humira®) *Abbott Laboratories* *Rheumatoid arthritis.*	Restricted use: adalimumab (Humira®) is accepted for restricted use within NHS Scotland for the treatment of rheumatoid arthritis (RA). It should be initiated only by specialist physicians experienced in the diagnosis and treatment of RA, and used in accordance with British Society Rheumatology (BSR) guidelines for prescribing TNF-∝ blockers in adults [which have been endorsed by the National Institute of Clinical Excellence (NICE) and QIS]. The BSR have established a Biologics Registry and details of patients treated with TNF-antagonists including adalimumab should be entered into this database. Adalimumab is the third TNF-antagonist licensed for the treatment of rheumatoid arthritis (RA).	Added to the Formulary, for Specialist Use only. Adalimumab is the third TNF-antagonist licensed for the treatment of rheumatoid arthritis. Efficacy is similar but has advantage over etanercept in dosing regimen. FC January 2004
May 2009 *NICE MTA 187* *Supersedes SMC Report No. 417/07*	adalimumab 40mg injection in pre-filled pen and syringe (Humira®) *Abbott Laboratories Ltd* *Treatment of severe, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.*	Adalimumab within its licensed indications, is recommended as treatment option for adults with severe active Crohn's disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed to determine whether ongoing treatment is still clinically appropriate.	Added to the Additional List, for Specialist Use only. FC September 2010
11.12.06 *SMC Report No. 300/06*	adalimumab 40mg pre-filled syringe (Humira®) *Abbott Laboratories Ltd* *Treatment of adults with severe active ankylosing spondylitis who have an inadequate response to conventional therapy.*	Restricted use: adalimumab (Humira®) is accepted for restricted use within NHS Scotland for the treatment of adults with severe active ankylosing spondylitis who have an inadequate response to conventional therapy. It is restricted to use in accordance with the British Society for Rheumatology (BSR) guidelines of July 2004. Adalimumab improves signs, symptoms, physical function and quality of life in patients with severe active ankylosing spondylitis. It reduces spinal inflammation, but there is no radiological evidence that it decreases joint damage. An economic evaluation demonstrated that it is a cost effective treatment option when used in tumour necrosis factor (TNF)-antagonist naïve patients in accordance with the BSR guidelines and where clear and rigorous stopping rules are applied.	Added to the Additional List, for Specialist Use only. FC October 2008
12.12.05 *SMC Report No. 218/05*	adalimumab 40mg pre-filled syringe for subcutaneous injection (Humira®) *Abbott* *New indication: treatment of active and progressive psoriatic arthritis in adults when response to disease-modifying anti-rheumatic drugs has been inadequate.*	Accepted for use: adalimumab (Humira®) is accepted for use within NHS Scotland for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Adalimumab improves symptoms of arthritis and psoriasis and may slow the progression of joint damage in patients with active psoriatic arthritis.	Added to the Formulary, for Specialist Use only. Adalimumab is an alternative for patients with psoriatic arthritis which is not controlled with two DMARDs or etanercept. FC January 2006

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09.06.08 *SMC Report No. 468/08*	adalimumab, 40mg solution for injection (Humira®) *Abbott Laboratories Ltd* *Treatment of chronic plaque psoriasis in adult patients who failed to respond to or have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA.*	Restricted use: adalimumab 40mg solution for injection (HumiraÒ) is accepted for restricted use within NHS Scotland for treatment of chronic plaque psoriasis in adult patients who failed to respond to or have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Its use should be restricted to patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score of ≥10 and a Dermatology Life Quality Index (DLQI) of >10. Adalimumab improves both signs and symptoms of psoriasis and quality of life compared to placebo and an active non-biological comparator. The manufacturer presented a sufficiently robust economic case to gain acceptance by the SMC for patients with severe disease who achieve a PASI 75 response from baseline at 16 weeks. Continuation of therapy beyond 16 weeks should be carefully reconsidered in patients not responding within this time period.	Added to the Additional List, for Specialist Use only. FC May 2010
09.02.09 *SMC Report No. 533/09* PRODUCT UPDATE (abbreviated submission)	adalimumab 40mg solution for injection (Humira®) *Abbott Laboratories* *Treatment of active polyarticular juvenile idiopathic arthritis in adolescents aged 13-17 years who have an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).*	Restricted use: adalimumab (Humira®) is accepted for restricted use in NHS Scotland, in combination with methotrexate, for the treatment of active polyarticular juvenile idiopathic arthritis in adolescents aged 13-17 years who have an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Adalimumab is one of three TNF-antagonists listed in the British National Formulary for Children as drugs that suppress the rheumatic disease process, and one of two of those drugs licensed for active polyarticular juvenile idiopathic arthritis. The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults.	Added to Additional List, Specialist Use only. FC August 2009
07.11.11 *SMC Report No. 738/11* PRODUCT UPDATE (abbreviated submission)	adalimumab (Humira®), 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use *Abbott Laboratories* *In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).*	Restricted use: adalimumab (Humira®) solution for injection is accepted for restricted use within NHS Scotland in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 4 years. It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations. The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adolescents aged 13 to 17 years and for rheumatoid arthritis in adults.	Added to the Additional List, for Specialist Use only. FC March 2012

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03.07.12 *SMC Report No. 800/12* NON SUBMISSION	adalimumab (Humira®) Pre-filled Pen, Pre-filled Syringe and Vial *Abbott Laboratories Limited* *Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.*	NOT RECOMMENDED: adalimumab (Humira®) is not recommended for use within NHS Scotland for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.11.12 *SMC Report No. 824/12* NON SUBMISSION	adalimumab (Humira®) *Abbott Laboratories* *Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.*	NOT RECOMMENDED: adalimumab (Humira®) is not recommended for use within NHS Scotland for the treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. Adalimumab remains a treatment option for adults with severe active Crohn's disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy, in line with the NICE (Multiple) Technology Appraisal Guidance No 187. Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.	NOT RECOMMENDED
08.04.13 *SMC Report No. 858/13*	adalimumab, 40mg/0.8mL, solution for injection (Humira®) *AbbVie Ltd* *Treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).*	Accepted for use: adalimumab (Humira®) is accepted for use within NHS Scotland for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). Adalimumab, compared to placebo, improves symptoms of severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults. Adalimumab should be prescribed in accordance with Assessment in Spondyloarthritis International Society (ASAS) guidance.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC July 2013

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08.07.13 *SMC Report No. 880/13* PRODUCT UPDATE (abbreviated submission)	adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) *AbbVie Limited* *For the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.*	Restricted use: adalimumab (Humira®) is accepted for restricted use within NHS Scotland for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies. SMC restriction: prescribing by specialists in paediatric gastroenterology. Treatment of paediatric patients with adalimumab resulted in similar clinical remission and response rates at weeks 26 and 52 to that achieved with adalimumab in severe active Crohn's disease in adults. Adalimumab has previously been accepted for use for this indication in adults with severe active Crohn's disease in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE Multiple Technology Appraisal No 187 was valid for Scotland.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC July 2013
08.07.13 *SMC Report No. 881/13* PRODUCT UPDATE (abbreviated submission)	adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®) *AbbVie Limited* *In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).*	Restricted use: adalimumab (Humira®) solution for injection is accepted for restricted use within NHS Scotland in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 2 years. SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations. The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in children and adolescents aged 4 to 17 years.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC July 2013
07.04.14 *SMC Report No. 682/11* RESUBMISSION Patient Access Scheme	adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) *Galderma UK Ltd* *Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present.*	Restricted use: adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) is accepted for restricted use within NHS Scotland as cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. SMC restriction: the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate. In 12-week studies, adapalene 0.1%/benzoyl peroxide 2.5% gel was as effective as an alternative combination antibiotic treatment in reducing inflammatory lesions. However adapalene 0.1%/benzoyl peroxide 2.5% gel was less well tolerated in terms of local reactions. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of adapalene 0.1%/benzoyl peroxide 2.5% gel. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC May 2014

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09.05.05 *SMC Report No. 54/03* RESUBMISSION	adefovir dipivoxil tablets 10mg (Hepsera®) *Gilead Sciences Ltd* *Chronic hepatitis B.*	Restricted use: adefovir dipivoxil (Hepsera®) is accepted for restricted use within NHS Scotland for the treatment of chronic hepatitis B in adults with either compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and fibrosis, or decompensated liver disease. Its use is restricted to patients who demonstrate lamivudine resistance.	Added to the Additional List. Shared care protocol. FC May 2005 Shared care protocol removed May 2012
10.10.11 *SMC Report No. 687/11* PRODUCT UPDATE (abbreviated submission	adrenaline tartrate 150 and 300 microgram solution for injection in a pre-filled pen (Jext®) *ALK-Abelló Ltd* *Emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.*	Accepted for use: Adrenaline tartrate (Jext®) is accepted for use within NHS Scotland emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis. For patients at risk of anaphylaxis and requiring adrenaline, this is a new presentation of adrenaline for emergency use. It has an extended shelf life (24 months) compared with some existing products.	Added to the formulary. **Included** on the Lothian Joint Formulary for indication in question. FC April 2012
10.03.14 *SMC Report No 920/13* Patient Access Scheme	afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®) *Boehringer Ingelheim International GmbH* *As monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s).*	Accepted for use: afatinib (Giotrif®) is accepted for use within NHS Scotland as monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). In two phase III studies, in patients with EGFR mutation positive adenocarcinoma of the lung, afatinib was significantly superior to the chemotherapy regimen comparators for the primary endpoint of progression free survival. Overall survival data are immature. A mixed treatment comparison provides indirect comparative data versus other tyrosine kinase inhibitors. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of afatinib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is erlotinib. FC February 2014
08.04.13 *SMC Report No 857/13* Patient Access Scheme	aflibercept 40mg/mL solution for intravitreal injection (Eylea®) *Bayer plc* *In adults for the treatment of neovascular (wet) age-related macular degeneration.*	Accepted for use: aflibercept (Eylea®) is accepted for use within NHS Scotland in adults for the treatment of neovascular (wet) age-related macular degeneration. In two pivotal randomised controlled studies the non-inferiority of aflibercept versus monthly injections of another anti-VEGF treatment was demonstrated for the primary endpoint; proportion of patients who maintained vision at week 52. The economic analysis submitted by the company related to the use of aflibercept in patients with wet AMD who have not previously been treated with anti-VEGF therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	**Included** on the Additional List, Specialist Use only for the indication in question. FC October 2013

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10.03.14 *SMC Report No 878/13* RESUBMISSION Patient Access Scheme	aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®) *Sanofi* *In combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.*	Accepted for use: aflibercept (Zaltrap®) is accepted for use within NHS Scotland in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen. In one randomised, double-blind, phase III study, aflibercept plus FOLFIRI chemotherapy regimen resulted in statistically significant longer overall survival compared with placebo plus FOLFIRI chemotherapy regimen. However the effect was of relatively modest clinical benefit. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC April 2014
07.04.14 *SMC Report No 954/14* Patient Access Scheme	aflibercept, 40mg/mL solution for injection (Eylea®) *Bayer* *For adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.*	Accepted for use: aflibercept intravitreal (Eylea®) is accepted for use within NHS Scotland for adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion. Two randomised double-masked studies demonstrated that aflibercept improved best corrected visual acuity significantly more than sham injections in treatment-naïve adults with macular oedema secondary to central retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC April 2014
13.09.10 *SMC Report No 564/09* RESUBMISSION	agomelatine, 25mg film-coated tablets (Valdoxan®) *Servier Laboratories UK Ltd* *Treatment of major depressive episodes in adults.*	NOT RECOMMENDED: agomelatine (Valdoxan®) is not recommended for use within NHS Scotland for the treatment of major depressive episodes in adults. When used in a flexible dosing schedule, agomelatine significantly reduced the symptoms of depression and increased the number of patients who responded to treatment compared with placebo. There are limited comparative data against existing antidepressants and the results of such comparisons are variable. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
08.09.08 *SMC Report No. 494/08*	alemtuzumab, 30mg/mL for concentrate for solution for infusion (MabCampath®) *Bayer plc, Bayer Schering Pharma Division* *Treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate.*	Restricted use: alemtuzumab (MabCampath®) is accepted for restricted use within NHS Scotland for treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate. It is restricted to use in patients with previously untreated B-CLL, with the cytogenetic abnormality 17p-deletion. Compared with an alkylating agent, alemtuzumab was associated with improved progression-free survival in patients with B-CLL. Data in patients with 17p-deletion are limited; improved survival was demonstrated in a sub-group analysis in 21 patients.	Added to the Additional List for Specialist use only. It has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC May 2011

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
07.07.14 *SMC Report No. 959/14*	alemtuzumab, 12mg, concentrate for solution for infusion (Lemtrada®) *Genzyme* *For adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.*	Accepted for use: alemtuzumab (Lemtrada®) is accepted for use within NHS Scotland for adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features. Two phase III studies comparing alemtuzumab with interferon beta-1a in treatment-naive (CARE-MS I) and treatment-experienced (CARE-MS II) patients with relapsing remitting multiple sclerosis both showed a statistically significant relative decrease in relapse rate of 55% and 49% respectively in favour of alemtuzumab. There was a significant reduction in the risk of sustained accumulation of disability over 6 months of 42% in CARE-MS II, but for CARE-MS-I, this was not statistically significant.	Formulary classification not yet decided – waiting for information from clinician.
07.11.05 *SMC Report No. 213/05*	alendronate 70mg, colecalciferol 2800IU tablet (Fosavance®) *Merck, Sharp and Dohme Ltd* *Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency who require treatment with both alendronate and vitamin D and for whom once-weekly administration is appropriate.*	Accepted for use: Alendronate/colecalciferol (Fosavance®) is accepted for use within NHS Scotland for the treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency who require treatment with both alendronate and vitamin D and for whom once-weekly administration is appropriate. The combination preparation is cost saving compared to the two drugs administered separately. Weekly administration of vitamin D represents a departure from routine clinical practice. In patients who also require calcium supplementation this will have to be administered separately, using a calcium preparation that does not also contain vitamin D.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC June 2008
12.03.07 *SMC Report No. 352/07*	alglucosidase alfa 50mg powder for concentrate for solution for infusion (Myozyme®) *Genzyme* *Treatment of Pompe disease (acid α-glucosidase deficiency).*	NOT RECOMMENDED: alglucosidase alfa (Myozyme®) is not recommended for use within NHS Scotland for the treatment of Pompe disease (acid α-glucosidase deficiency). Treatment in patients with the infantile-form of Pompe disease significantly improved survival compared with historical controls. The evidence is less clear for patients who are already receiving ventilatory support or who have the late-onset form of the disease. The economic case has not been demonstrated. The SMC orphan drug policy requires manufacturers to make complete submissions to allow a comprehensive product assessment similar to all other drug submissions. However, in addition to the usual assessment of clinical and cost effectiveness, SMC may consider additional factors specific to orphan products. Within this context the particular features of the condition and population receiving the technology and whether a drug can reverse (rather than stabilise) the condition or bridge a gap to a definitive therapy may also be considered. SMC considered the submission in the context of its orphan drug policy.	NOT RECOMMENDED
08.02.10 *SMC Report No. 462/08* RESUBMISSION	aliskiren (Rasilez®) *Novartis Pharmaceutical UK Ltd* *Treatment of essential hypertension.*	NOT RECOMMENDED: aliskiren (Rasilez®) is not recommended for use within NHSScotland for the treatment of essential hypertension. Aliskiren has shown comparable efficacy to other antihypertensive agents in terms of blood pressure reduction, though its effects on mortality and long-term morbidity are currently unknown. The manufacturer did not present a sufficiently robust clinical or economic analysis to gain acceptance by SMC for the position sought.	NOT RECOMMENDED

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09.03.09 *SMC Report No. 538/09*	alitretinoin 10mg, 30mg capsules (Toctino®) *Basilea Pharmaceuticals Ltd* *Severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids.*	Accepted for use: alitretinoin (Toctino®) is accepted for use within NHS Scotland in adults who have severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids. Evidence is limited to a randomised placebo-controlled study where alitretinoin was superior to placebo in terms of the primary endpoint, Physician Global Assessment of response. It is recommended that alitretinoin is dispensed by a hospital-based pharmacy.	Added to the Additional List, for Specialist Use only. FC July 2009 The above FC decision remaines unchanged. FC April 2013
10.03.14 *SMC Report No. 937/14*	alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®) *Takeda Pharma A/S* *For adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.*	NOT RECOMMENDED: alogliptin (Vipidia®) is not recommended for use within NHS Scotland for adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. Treatment with alogliptin reduces glycosylated haemoglobin, HbA1c, significantly more than placebo when used in combination with metformin or sulfonylurea. There are no clinical studies of alogliptin, as triple therapy, in combination with metformin and sulfonylurea. The submitting company did not present sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
08.03.04 *SMC Report No. 87/04*	alteplase (Actilyse®) *Boehringer Ingelheim* *New indication: Treatment of acute ischaemic stroke.*	Restricted use: alteplase (rt-PA) (Actilyse) is accepted for restricted use within NHS Scotland for the treatment of acute ischaemic stroke. Alteplase is licensed in the UK for the early treatment of acute ischaemic stroke, but there are potentially fatal risks incurred in using this treatment. The use of alteplase is therefore confined to specialist centres with adequate resources and appropriate expertise. It is associated with an increased risk of intracerebral haemorrhage including fatal haemorrhage and must be used strictly in accordance with detailed protocols specifying the availability of appropriate expertise and resources, including computerised tomography or magnetic resonance imaging in order to exclude haemorrhagic stroke. Treatment centres must participate in the post-marketing surveillance study SITS-MOST (Safe Implementation of Thrombolysis in Stroke Monitoring Study) designed to determine whether alteplase is as safe and beneficial in routine clinical practice as has been shown in the clinical trial setting.	Added to the Formulary. Alteplase is the only thrombolytic licensed for acute ischaemic stroke. Treatment must be started within 3 hours of onset of symptoms and in strict accordance with detailed protocols in Specialist centres. FC May 2004
08.08.11 *SMC Report No: 717/11* PRODUCT UPDATE (abbreviated submission)	alteplase 2mg powder and solvent for solution for injection for infusion (Actilyse Cathflo®) *Boehringer Ingelheim* *Thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.*	Restricted use: alteplase 2mg powder and solvent for solution for injection (Actilyse Cathflo®) is accepted for restricted use within NHS Scotland. Indication under review: thrombolytic treatment of occluded central venous access devices including those used for haemodialysis. SMC restriction: to use where alteplase is the product of choice for the treatment of occluded venous access devices. This is a new formulation introduced for this extension to the alteplase marketing authorisation and the 2-mL vial is the only presentation licensed for this indication.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.06.12 *SMC Report No. 714/11*	alteplase, 10mg, 20mg, 50mg, powder and solvent for solution for injection and infusion (Actilyse®) *Boehringer Ingelheim* *For the fibrinolytic treatment of acute ischaemic stroke.*	Accepted for use: alteplase (Actilyse®) is accepted for use within NHS Scotland for the fibrinolytic treatment of acute ischaemic stroke. Treatment must be started as early as possible within 4.5 hours after onset of the stroke symptoms and after exclusion of intracranial haemorrhage by appropriate imaging techniques (e.g. cranial computerised tomography or other diagnostic imaging method sensitive for the presence of haemorrhage). Evidence for the extension of the time window in which alteplase can be administered is from a placebo-controlled study. Alteplase treatment resulted in significantly more patients having no symptoms or no significant disabling symptoms at three months compared to placebo.	**Included** on the LJF for the indication in question, Specialist Use only. FC November 2012
10.11.08 *SMC Report No. 511/08*	ambrisentan, 5mg and 10mg tablets (Volibris®) *GlaxoSmithKline* *Treatment of patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease.*	Restricted use: ambrisentan 5mg and 10mg tablets (Volibris®) is accepted for restricted use within NHS Scotland for the treatment of patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease. Data suggest that ambrisentan has a benefit/risk ratio comparable to other endothelin receptor antagonists. Non-inferiority has not been formally demonstrated as ambrisentan is an orphan drug with limited clinical evidence. Where an endothelin receptor antagonist is indicated, ambrisentan provides an alternative. It is restricted to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or similar specialists.	Approved for use – patients receive prescriptions from the Scottish Pulmonary Vascular Unit FC August 2009
13.08.12 *SMC Report No. 660/10*	amifampridine 10mg tablet, as phosphate (Firdapse®) *BioMarin UK Ltd* *Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.*	NOT RECOMMENDED: amifampridine phosphate (Firdapse®) is not recommended for use within NHS Scotland for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. There are no clinical data for amifampridine phosphate and efficacy has been extrapolated from studies of amifampridine base (3,4-diaminopyridine), to which amifampridine phosphate has been accepted to be bioequivalent by the European Medicines Agency. In randomised controlled studies in patients with LEMS, 3,4-diaminopyridine treatment was associated with greater improvement in muscle strength and neuromuscular transmission than placebo. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.03.07 *SMC Report No. 350/07* PRODUCT UPDATE (abbreviated submission)	amlodipine / valsartan 5mg/80mg, 5mg/160mg, 10mg/160mg (Exforge®) tablet *Novartis Pharmaceuticals UK Ltd* *For patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy.*	Accepted for use: amlodipine/valsartan (Exforge®) is accepted for use in NHS Scotland for patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy. In patients for whom concomitant use of these medicines as a fixed dose combination is appropriate it allows administration of a single tablet at no greater cost than valsartan (Diovan®) alone. Angiotensin receptor blockers are an alternative to ACE inhibitors where these are not tolerated. This fixed dose combination is one of many options for the treatment of hypertension, many of which are less expensive.	'Not preferred' as suitable alternatives exist. FC October 2007
10.10.05 *SMC Report No. 163/05* RESUBMISSION	anagrelide 0.5mg capsule (Xagrid®) *Shire* *Essential thrombocythaemia.*	Accepted for use: anagrelide (Xagrid®) is accepted for use within NHS Scotland for the reduction of elevated platelet counts in at-risk patients with essential thrombocythaemia who are intolerant of their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy. Anagrelide reduces platelet counts in patients with essential thrombocythaemia who were intolerant of another cytoreductive therapy or whose platelet count could not be controlled by it.	Added to the Additional List, for Specialist Use only. FC November 2005

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08.11.02 *SMC Report No. 05/02* REVIEW ASSESSMENT	anakinra, human recombinant interleukin-1 receptor antagonist (Kineret®) *Amgen* *Rheumatoid Arthritis.*	NOT RECOMMENDED: anakinra, human recombinant interleukin-1 receptor antagonist (Kineret®) is not recommended for use in NHS Scotland. The company have produced no additional data to indicate a susceptible target population for this biological product which does not appear to be as effective as competitor products, and is not particularly cost effective.	NOT RECOMMENDED
12.09.05 *SMC Report No. 198/05*	anastrazole 1mg tablets (Arimidex®) *AstraZeneca UK Ltd* *New indication: for adjuvant treatment of postmenopausal women with hormone receptor-positive early invasive breast cancer.*	Restricted use: anastrozole (Arimidex®) is accepted for restricted use within NHS Scotland in the adjuvant treatment of postmenopausal women with hormone receptor-positive early invasive breast cancer. Anastrozole has shown benefit over standard anti-oestrogen therapy in terms of disease-free survival in this patient group. It offers an alternative to tamoxifen and has a different adverse effects profile. Treatment with anastrozole should be initiated by a breast cancer specialist.	Added to LJF as 2nd choice treatment for patients at risk of early recurrence or with contraindication to tamoxifen. FC August 2010
13.11.06 *SMC Report No. 322/06*	anastrozole 1mg tablet (Arimidex®) *AstraZeneca UK Limited* *Adjuvant treatment of early breast cancer in hormone receptor positive postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen.*	Restricted use: anastrozole (Arimidex®) is accepted for restricted use within NHS Scotland for the adjuvant treatment of early breast cancer in hormone receptor positive postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen. In a combined analysis of two trials, switching to anastrozole after 2 years of tamoxifen therapy rather than continuing with tamoxifen resulted in a 3.1% increase in event-free survival at three years follow-up. It offers an alternative to tamoxifen after initial adjuvant treatment with tamoxifen for 2-3 years and has a different adverse effects profile. Treatment with anastrozole is restricted to initiation by a breast cancer specialist.	'Not preferred' in Lothian as suitable alternatives exist. Note; this relates to this indication only. FC August 2010
10.11.08 *SMC Report No. 465/08* RESUBMISSION	anidulafungin 100mg powder and solvent for concentrate for solution for infusion (Ecalta®) *Pfizer Ltd* *Treatment of invasive candidiasis in adult non-neutropenic patients.*	Restricted use: anidulafungin (Ecalta®) is accepted for restricted use within NHS Scotland for the treatment of invasive candidiasis in adult non-neutropenic patients. Anidulafungin has been shown to be at least as effective as an alternative antifungal in a study of patients, the majority of whom had candidaemia. Its use is restricted to patients who are unable to tolerate fluconazole or have invasive candidiasis that is resistant to fluconazole.	Added to the Additional List, for Specialist Use only. FC August 2011
12.12.11 *SMC Report No. 741/11*	apixaban 2.5mg film-coated tablet (Eliquis®) *Bristol-Myers Squibb Pharmaceuticals Ltd/Pfizer Ltd.* *Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.*	Accepted for use: apixaban (Eliquis®) is accepted for use within NHS Scotland for prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. In two large phase III double-blind comparative studies, in patients undergoing elective hip or knee replacement surgery, apixaban was superior to a low molecular weight heparin for the incidence of VTE and all cause death whilst incidence of major bleeding events was similar between groups.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. FC July 2012

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11.02.13 *SMC Report No. 836/13*	apixaban 2.5mg and 5mg film-coated tablets (Eliquis®) *Bristol-Myers Squibb / Pfizer* *For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II).*	Accepted for use: apixaban (Eliquis®) is accepted for use within NHS Scotland for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II). Apixaban was superior to standard oral anticoagulation at preventing stroke or systemic embolism in one large, double-blind study in patients with atrial fibrillation and at least one risk factor for stroke. It was also associated with a significant reduction in risk of major bleeding.	**Included** on the LJFas a second choice drug for the indication in question. FC April 2013
08.11.04 *SMC Report No. 132/04*	aprepitant (Emend®) *Merck, Sharpe & Dohme* *Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy.*	Restricted use: aprepitant (Emend®) is accepted for restricted use within NHS Scotland for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy. The antiemetic regimen incorporating aprepitant was superior to one regimen (where dexamethasone alone was used in the delayed phase of treatment), for the prevention of cisplatin-induced nausea and vomiting in the acute and delayed phases. It should be initiated only by appropriate hospital based specialists.	Added to the Additional List, for Specialist Use only. FC July 2008
07.11.11 *SMC Report No. 242/06* RESUBMISSION	aprepitant 80mg, 125mg hard capsules (Emend®) *Merck Sharp and Dohme Ltd* *For prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.*	NOT RECOMMENDED: aprepitant (Emend®) as part of combination therapy is not recommended for use within NHS Scotland for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. Compared with a control regimen, aprepitant has been shown to increase the proportion of patients achieving a complete response in a study of breast cancer patients or experiencing no vomiting in patients with a range of tumour types, when patients were initiated on their first cycle of a moderately emetogenic chemotherapy regimen. However the control regimen was considered suboptimal for the treatment of delayed symptoms and evidence for use in subsequent cycles is limited. Overall the submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	NOT RECOMMENDED
12.08.13 *SMC Report No. 812/12* RESUBMISSION	argatroban, 100mg/mL, concentrate for solution for infusion (Exembol®) *Mitsubishi Pharma Europe Ltd* *Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.*	Accepted for use: argatroban (Exembol®) is accepted for use within NHS Scotland for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy. Argatroban produces anticoagulant effects in adults with heparin-induced thrombocytopenia type II. However there is limited evidence that the anticoagulant effects are associated with a reduction in thrombosis and deaths due to thrombosis.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC August 2013

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
09.08.04 *SMC Report No. 95/04*	aripiprazole (Abilify®) *Bristol-Myers Squibb / Otsuka* *Schizophrenia.*	Accepted for use: aripiprazole (Abilify®) is accepted for use within NHS Scotland for the treatment of schizophrenia. It is one of several atypical antipsychotic medicines that improve symptoms of an acute relapse and reduce the risk of relapse comparable to a typical antipsychotic. The evidence of comparable efficacy to other atypical antipsychotics is limited. It is associated with a lower incidence of extra-pyramidal side effects than typical antipsychotics, and comparable to other atypicals. It is associated with less elevation of serum prolactin, less lipid abnormalities and less clinically significant weight gain over the short-term compared with other atypical antipsychotics. It does not adversely effect blood glucose nor have a clinically significant advantage compared to other antipsychotics with respect to this.	Added to the Additional List, for Specialist Use only. Use of aripiprazole and all atypical antipsychotics to be reviewed September 2005 with view to producing shared care protocol if appropriate. FC August 2004
11.07.05 *SMC Report No. 187/05* PRODUCT UPDATE (abbreviated submission)	aripiprazole (Abilify®) 5mg tablets *Bristol-Myers Squibb* *Schizophrenia.*	Restricted use: aripiprazole tablets 5mg (Abilify®) are accepted for restricted use in NHS Scotland for the treatment of schizophrenia. Where aripiprazole is an appropriate antipsychotic, this new dosage is restricted to patients who may benefit from a dose reduction to 5mg daily, taking account of SMC advice issued in August 2004. This 5mg tablet is the same price as the 10mg and 15mg tablets.	Added to the Additional List, for Specialist Use only. New strength of tablet already classified as Additional List.
08.06.09 *SMC Report No. 498/08* RESUBMISSION	aripiprazole 5mg, 10mg, 15mg, 30mg tablets; 10mg, 15mg orodispersible tablets; 1mg/mL oral solution (Abilify®) *Bristol-Myers Squibb Pharmaceuticals Ltd, Otsuka Pharmaceuticals (UK) Ltd* *Treatment of moderate to severe manic episodes in bipolar I disorder and for the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment.*	NOT RECOMMENDED: aripiprazole oral formulations (Abilify®) are not recommended within NHS Scotland for the treatment of moderate to severe manic episodes in bipolar I disorder and for the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment. Aripiprazole demonstrated superior efficacy to placebo in reducing manic symptoms at week three and a treatment effect comparable to other agents used in the treatment of bipolar I disorder was maintained at week 12. Aripiprazole also demonstrated superior efficacy to placebo in prevention of relapse. Aripiprazole has not been directly compared to other atypical antipsychotics in this indication, although there is only one other atypical antipsychotic licensed for prevention of new manic episodes. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
08.12.08 *SMC Report No. 522/08* PRODUCT UPDATE (abbreviated submission)	aripiprazole solution for intramuscular injection 7.5mg/mL in a 9.75mg vial (Abilify®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *For rapid control of agitation and disturbed behaviours in patients with schizophrenia.*	Accepted for use: aripiprazole intramuscular injection (Abilify®) is accepted for use in NHS Scotland for the rapid control of agitation and disturbed behaviours in patients with schizophrenia when oral therapy is not appropriate. Where aripiprazole is an appropriate antipsychotic, this new formulation provides rapid control of symptoms at an equivalent cost to solid oral dosage forms. SMC has not recommended aripiprazole for use within NHS Scotland for the treatment of manic episodes in bipolar 1 disorder. Therefore this formulation is not recommended for the rapid control of agitation and disturbed behaviours in patients with manic episodes in bipolar 1 disorder.	'Not preferred' in Lothian as suitable alternatives exist. FC November 2009

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
09.08.10 *SMC Report no. 630/10* PRODUCT UPDATE (abbreviated submission)	aripiprazole 5, 10, 15, 30mg oral tablets, 10, 15mg orodisperible tablets and 1mg/1mL oral solution(Abilify®) *Bristol-Myers Squibb* The treatment of schizophrenia in adolescents 15 years and older.	Restricted use: aripiprazole tablets, orodisperible tablets and oral solution (Abilify®) are accepted for restricted use within NHS Scotland. Indication under review: The treatment of schizophrenia in adolescents 15 years and older. SMC restriction: Restricted to initiation and management under the supervision of a child/adolescent psychiatrist. Aripiprazole has demonstrated short and long-term efficacy in adolescents in the 15 to 17 year old subgroup which is similar to that observed in the adult patient population. The Scottish Medicines Consortium has previously accepted this product for use in schizophrenia in adults. Aripiprazole is one of several atypical antipsychotic medicines that improve symptoms of an acute relapse and reduce the risk of relapse comparable to a typical antipsychotic. The evidence of comparable efficacy to other atypical antipsychotics is limited. It is associated with a lower incidence of extra-pyramidal side effects than typical antipsychotics, and comparable to other atypicals. It is associated with less elevation of serum prolactin, less lipid abnormalities and less clinically significant weight gain over the short-term compared with other atypical antipsychotics. It does not adversely effect blood glucose nor have a clinically significant advantage compared to other antipsychotics with respect to this.	Added to the Additional List, for Specialist Use only for use in children 15 years and older. FC August 2010
09.09.13 *SMC Report No. 891/13*	aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®) *Otsuka Pharmaceutical (UK) Ltd* *Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older.*	Restricted use: aripiprazole oral (Abilify®) is accepted for restricted use within NHS Scotland for the treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. SMC restriction: restricted to initiation and management under the supervision of a child/adolescent psychiatrist. Aripiprazole demonstrated superior efficacy to placebo in reducing manic symptoms at 4 weeks. Aripiprazole has not been directly compared to other atypical antipsychotics, none of which are licensed for this indication although they are used off-label in clinical practice.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC May 2014
12.05.14 *SMC Report No. 962/14*	aripiprazole 400mg powder and solvent for prolonged release suspension for injection (Abilify Maintena®) *Otsuka Pharmaceuticals and Lundbeck Ltd* *Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.*	Accepted for use: aripiprazole prolonged release suspension for injection (Abilify Maintena®) is accepted for use within NHS Scotland for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole. In a comparative study, aripiprazole prolonged release suspension for injection was as effective as oral aripiprazole in reducing the risk of impending relapse over 26 weeks in stabilised schizophrenic patients. Weaknesses in the indirect comparison limit the reliability of relative efficacy and safety with prolonged release injection forms of other atypical antipsychotics.	**Not included** on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine. FC July 2014

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12.03.12 *SMC Report No. 762/12*	asenapine 5mg, 10mg sublingual tablet (Sycrest®) *Lundbeck Ltd* *For the treatment of moderate to severe manic episodes associated with bipolar I disorder, in adults.*	NOT RECOMMENDED: asenapine (Sycrest®) is not recommended for use within NHS Scotland for the treatment of moderate to severe manic episodes associated with bipolar I disorder, in adults. Asenapine when used as monotherapy demonstrated superior efficacy to placebo in reducing manic symptoms as measured using the Young Mania Rating Score at three weeks with maintenance of effect at 12 weeks. In addition, asenapine in combination with lithium or valproate demonstrated superior efficacy to lithium or valproate monotherapy. There are no direct comparative data when asenapine is used as add-on treatment. Indirect comparisons with other second generation antipsychotic agents used as monotherapy and as adjunctive therapy suggested equivalent efficacy. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
13.09.04 *SMC Report No. 120/04*	atazanavir (Reyataz®) *Bristol-Myers Squibb* *Antiretroviral.*	Restricted use: atazanavir (Reyataz®) is accepted for restricted use within NHS Scotland for the treatment of HIV-1 infected, antiretroviral treatment experienced adults, in combination with other antiretroviral medicinal products in those patients who do not require concomitant statin use. The combination of atazanavir and ritonavir was non-inferior to a standard boosted protease inhibitor (PI) regimen in patients with moderate previous exposure to PIs, however, it was inferior in patients with PI-resistant viruses. It was associated with lower incidences of diarrhoea and lipid adverse-effects and a higher incidence of hyperbilirubinaemia. The health economic case for use is acceptable when atazanavir is compared with a standard boosted protease inhibitor regime in patients receiving concomitant statins.	Added to the Additional List. Specialist Use only in line with recommendations for other antiretroviral therapy. FC November 2004
12.01.09 *SMC Report No. 520/08* AMENDED ADVICE	atazanavir, 300mg capsules (Reyataz®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *Treatment naïve HIV-1 infected adults in combination with other antiretroviral medicinal products.*	Accepted for use: atazanavir (Reyataz®) is accepted for use within NHS Scotland in antiretroviral treatment naïve HIV-1 infected adults in combination with other antiretroviral medicinal products. The combination of atazanavir and ritonavir was non-inferior to a standard boosted protease inhibitor regimen in treatment naïve HIV patients. The combined regimen was associated with lower incidences of diarrhoea and lipid adverse-effects and a higher incidence of hyperbilirubinaemia in this patient population.	Added to the Additional List, for Specialist Use only. FC August 2010
13.12.10 *SMC Report No. 656/10* PRODUCT UPDATE (abbreviated submission)	atazanavir 150, 200 and 300mg capsules (Reyataz®) *Bristol Myers Squibb Pharmaceuticals* *Co-administered with low dose ritonavir, is indicated for the treatment of paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products..*	Accepted for use: atazanavir (Reyataz®) is accepted for use within NHS Scotland. Indication under review: atazanavir, co-administered with low dose ritonavir, is indicated for the treatment of paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products. Data available in children aged 6 to less than 18 years are very limited. Available data suggest that atazanavir in combination with ritonavir may not be effective in treatment experienced children even with very few (<3) protease inhibitor mutations. The choice of atazanavir in treatment experienced paediatric patients should be based on individual viral resistance testing and the patient's treatment history. The Scottish Medicines Consortium has previously accepted this product for use in HIV infection in adults. Atazanavir is listed in the British National Formulary for Children 2010 -11 for the treatment of HIV.	Added to the Additional List, for Specialist Use only. FC December 2010

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11.07.05 *SMC Report No. 153/05* RESUBMISSION	atomoxetine capsules 10mg to 60mg (Strattera®) *Eli Lilly & Company Ltd* *ADHD.*	Restricted use: atomoxetine (Strattera®) is accepted for restricted use within NHS Scotland for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older or in adolescents. It is restricted to use in patients who do not respond to stimulants or in whom stimulants are contraindicated or not tolerated. It is restricted to use by physicians with appropriate knowledge and expertise in treating ADHD. This advice concerns use in children and adolescents only and does not cover use in adults. Atomoxetine (Strattera) it is not a Controlled Drug under the Misuse of Drugs regulations 2001.	Added to the LJF for Children as a Prescribing Note, for patients who do not respond to stimulants, e.g. dexamfetamine, methylphenidate, or in whom stimulants are contra-indicated or not tolerated. The first choice drug for ADHD in the Formulary is methylphenidate and second choice is dexamfetamine. FC August 2005
11.11.13 *SMC Report No. 909/13*	atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®) *Eli Lilly and Company* *Treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme.*	Accepted for use: atomoxetine (Strattera®) is accepted for use within NHS Scotland for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed. Short term studies in adults have shown that atomoxetine improves symptoms of ADHD compared to placebo. The economic case for atomoxetine has been demonstrated for a treatment duration of one year.	**Included** on the LJF as a second choice drug, for Specialist Initiation, for the indication in question. FC December 2013
10.11.03 *SMC Report No. 58/03* PRODUCT UPDATE (abbreviated submission	Avonex® Liquid (Interferon beta 1a) *Biogen Ltd* *Treatment of selected ambulatory patients with relapsing-remitting multiple sclerosis.*	Restricted use: Avonex® Liquid (Interferon beta 1a) is accepted for restricted use within NHS Scotland. Avonex is a liquid formulation which replaces a powder formulation of the same strength that requires reconstitution. It is supplied at the same price. This product is used for the treatment of selected ambulatory patients with relapsing-remitting multiple sclerosis under the provision of a risk-sharing scheme between the Scottish Executive and the manufacturer.	A new formulation of a drug already included in the Formulary. This is a new formulation of interferon beta which is used for the treatment of multiple sclerosis (Specialist Use only) in selected patients as part of the MS risk-sharing scheme. FC November 2003
10.10.05 *SMC Report No. 202/05* PRODUCT UPDATE (abbreviated submission)	atorvastatin (Lipitor®) *Pfizer Ltd* *Hypercholesterolaemia in children.*	Restricted use: atorvastatin calcium (Lipitor®) is accepted for restricted use in the NHS in Scotland as an adjunct to diet for the reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B and triglycerides in children aged 10 years and older with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia or combined (mixed) hyperlipidaemia when response to diet and other non-pharmacological measures is inadequate. It is restricted to initiation by paediatricians or physicians specialising in the management of lipid disorders.	Added to the LJF for Children as first choice. FC September 2006

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12.03.12 *SMC Report No. 766/12* PRODUCT UPDATE (abbreviated submission)	atorvastatin 10 and 20mg chewable tablets (Lipitor®) *Pfizer Ltd* *See in next coloumn.*	Accepted for use: atorvastatin chewable tablets (Lipitor®) is accepted for use in NHS Scotland as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate; to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable; prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors. Atorvastatin chewable tablets have demonstrated bioequivalence to atorvastatin film-coated tablets (Lipitor®) and are available at an equivalent cost. However less expensive generic preparations of atorvastatin tablets are expected to become available in the near future.	Add to the LJF as a prescribing note. FC March 2012
09.06.14 *SMC Report No. 980/14* NON SUBMISSION	avanafil (Spedra®) 50mg, 100mg and 200mg tablets *A Menarini Farmaceutica Internazionale SRL* *Treatment of erectile dysfunction in adult men.*	NOT RECOMMENDED: avanafil (Spedra®) is not recommended for use within NHS Scotland for the treatment of erectile dysfunction in adult men. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. The sponsor company plans to make a submission to SMC in November 2014.	NOT RECOMMENDED
11.11.13 *SMC Report No. 855/13* RESUBMISSION Patient Access Scheme	axitinib, 1mg and 5mg, film-coated tablets (Inlyta®) *Pfizer* *For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.*	Accepted for use: axitinib (Inlyta®) is accepted for use within NHS Scotland for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. In a phase III, open-label study, axitinib improved progression-free survival significantly more than another targeted therapy when used after first-line sunitinib or a cytokine. There was no significant improvement in overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of axitinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC December 2013

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12.09.11 *SMC Report No. 589/09* RESUBMISSION Patient Access Scheme	azacitidine 100mg powder for suspension for injection (Vidaza®) *Celgene Ltd* *Treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with:* • *intermediate-2 and high-risk myelodysplastic syndrome (MDS) according to the International Prognostic Scoring System (IPSS)* • *chronic myelomonocytic leukaemia (CMML) with 10–29% marrow blasts without myeloproliferative disorder* • *acute myeloid leukaemia (AML) with 20–30% blasts and multilineage dysplasia, according to the World Health Organisation classification*	Accepted for use: azacitidine (Vidaza®) is accepted for use within NHS Scotland for treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with intermediate-2 and high-risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML). Azacitidine therapy produced a significant increase in overall survival compared with conventional care regimens in previously untreated higher-risk MDS patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of azacitidine. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only. FC November 2011
07.05.07 *SMC Report No. 359/07*	azelaic acid 15% gel (Finacea®) *Valeant Pharmaceuticals Ltd* *Topical treatment of papulopustular rosacea*	Accepted for use: azelaic acid 15% gel (Finacea®) is accepted for use within NHS Scotland for the topical treatment of papulopustular rosacea. It shows equivalent efficacy at a lower cost compared to another topical preparation used for rosacea.	Added to the LJF as first choice for the treatment of papulopustular rosacea. FC January 2008
09.12.13 *SMC Report No. 921/13* PRODUCT UPDATE (abbreviated submission)	azelastine hydrochloride 137micrograms plus fluticasone propionate 50micrograms per actuation nasal spray (Dymista® nasal spray) *Meda Pharmaceuticals* *For the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.*	NOT RECOMMENDED: azelastine hydrochloride plus fluticasone propionate nasal spray (Dymista®) is not recommended for use within NHS Scotland for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient. The combined azelastine and fluticasone nasal spray is significantly more expensive than the components administered separately.	NOT RECOMMENDED
03.07.12 *SMC Report No. 803/12* NON SUBMISSION	azilsartan medoxomil (Edarbi®) 20mg, 40 mg and 80mg tablets *Takeda* *Treatment of essential hypertension in adults.*	NOT RECOMMENDED: azilsartan medoxomil (Edarbi®) is not recommended for use within NHS Scotland for the treatment of essential hypertension in adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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03.07.12 *SMC Report No. 804/12* NON SUBMISSION	azithromycin dihydrate (Azyter®) 15 mg/g, eye drops, solution in single-dose container *Spectrum Thea Pharmaceuticals Limited* *Local antibacterial treatment of conjunctivitis caused by susceptible strains:* *- Purulent bacterial conjunctivitis,* *- Trachomatous conjunctivitis caused by Chlamydia trachomatis.*	NOT RECOMMENDED: azithromycin dihydrate (Azyter®) is not recommended for use within NHS Scotland as local antibacterial treatment of conjunctivitis caused by susceptible strains: - Purulent bacterial conjunctivitis, - Trachomatous conjunctivitis caused by Chlamydia trachomatis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.04.14 *SMC Report No. 950/14* PRODUCT UPDATE (abbreviated submission)	azithromycin 500mg powder for solution for infusion (Zedbac®) *Aspire Pharma Limited* *The treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required.*	Accepted for use: azithromycin (Zedbac®) is accepted for use within NHS Scotland for the treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required. Consideration should be given to official guidance regarding the appropriate use of antibacterial agents. This is the first intravenous formulation of azithromycin to be made available in the UK. The intravenous formulation is significantly more expensive than the oral preparation of azithromycin, but it is intended only for short-term use and on the advice of local microbiologists or specialists in infectious diseases.	**Included** on the Additional List, for Specialist Use only, for the indication in question. Azithromycin has been classified as an alert antibiotic. FC April 2014
13.02.12 *SMC Report No. 753/12* AMENDED ADVICE	aztreonam lysine 75mg powder and solvent for nebuliser solution (Cayston®) *Gilead Sciences Limited* *The suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older.*	NOT RECOMMENDED: aztreonam lysine (Cayston®) is not recommended for use within NHS Scotland for the suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older. Aztreonam lysine has demonstrated superiority in improving lung function and respiratory symptoms in one 28-day active-controlled study and two 28-day placebo-controlled studies in patients with cystic fibrosis and chronic Pseudomonas aeruginosa infection. There are limited data to support the sustainability of the observed short term benefit over subsequent courses of treatment. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and, in addition, the company did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED

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14.01.08 *SMC Report No. 373/07* PRODUCT UPDATE (abbreviated submission)	beclometasone 100micrograms, formoterol 6micrograms metered dose inhaler (Fostair®) T*rinity-Chiesi Pharmaceuticals Ltd* *Regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta$_2$-agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta$_2$-agonist; or patients already adequately controlled on both inhaled corticosteroids and long-acting beta$_2$-agonists.*	Accepted for use: beclometasone 100micrograms, formoterol 6micrograms metered dose inhaler (Fostair®) is accepted for use within NHS Scotland for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta$_2$-agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta$_2$-agonist; or patients already adequately controlled on both inhaled corticosteroids and long-acting beta$_2$-agonists. It should be used in patients for whom beclometasone and formoterol are appropriate choices of corticosteroid and long-acting beta-agonist, respectively, and for whom a metered dose inhaler is an appropriate delivery device. It has costs similar to other combination products containing a corticosteroid and long-acting beta$_2$-agonist to which it was clinically non-inferior. The 100micrograms dose of beclometasone in Fostair® is not bioequivalent to a 100micrograms dose of beclometasone in several other inhaler formulations. The Fostair® summary of product characteristics contains information on transferring from these inhalers to Fostair®.	Added to the Formulary. FC April 2010
07.08.06 *SMC Report No. 177/05* PRODUCT UPDATE (abbreviated submission)	beclometasone dipropionate (Clenil Modulite®) *Trinity-Chiesi Pharmaceuticals Ltd* *Prophylactic management of mild, moderate or severe asthma in adults or children.*	Accepted for use: The Clenil Modulite® range of inhalers is accepted for use in NHS Scotland for the prophylactic management of mild, moderate or severe asthma in adults or children. They provide chlorofluorocarbon (CFC)-free inhalers with dose equivalence to CFC-containing inhalers. The cost is similar to another (CFC)-free inhaler, however doses are not equivalent to the other CFC-free inhaler product currently available.	Added to the formulary as first choice beclometasone CFC-free inhaler. FC January 2008
10.09.07 *SMC Report No. 166/05*	beclometasone dipropionate 5mg tablets (Clipper®) *Trinity-Chiesi Pharmaceuticals* *Treatment of mild to moderate ulcerative colitis in active phase as add-on therapy to 5-ASA containing drugs.*	NOT RECOMMENDED: Beclometasone dipropionate (Clipper®) is not recommended for use within NHS Scotland for the treatment of mild to moderate ulcerative colitis in active phase as add-on therapy to 5-ASA containing drugs. The clinical and cost effectiveness against standard practice have not been demonstrated. This advice is based on an assessment carried out in April 2005. The licence holder has indicated their intention to resubmit.	NOT RECOMMENDED
07.07.14 *SMC Report No. 976/14* PRODUCT UPDATE (abbreviated submission)	beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) *Chiesi Ltd* *Symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators*.	Accepted for use: beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) is accepted for use within NHS Scotland for symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. Fostair® should be used in patients for whom beclometasone and formoterol are appropriate choices of corticosteroid and long-acting beta$_2$-agonist respectively, and for whom a metered dose inhaler is an appropriate delivery device. The introduction of Fostair® is likely to be cost neutral. The 100mcg dose of beclometasone in Fostair® is not bioequivalent to a 100mcg dose of beclometasone in several other inhaler formulations.	**Not included** on the LJF, pending protocol. FC July 2014

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11.06.12 *SMC Report No. 786/12*	belatacept powder for concentrate for solution for infusion 250mg vial and disposable syringe (Nulojix®) *Bristol Myers Squibb Pharmaceuticals Ltd* *In combination with corticosteroids and mycophenolic acid, is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin-2 receptor antagonist for induction therapy to this belatacept-based regimen.*	NOT RECOMMENDED: belatacept (Nulojix®) is not recommended for use within NHS Scotland in combination with corticosteroids and mycophenolic acid, is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin-2 receptor antagonist for induction therapy to this belatacept-based regimen. Results of two phase III studies have demonstrated comparable graft and patient survival of belatacept versus a calcineurin inhibitor when used as part of a maintenance immunosuppressive regimen. Indirect efficacy data from a mixed treatment comparison are available for belatacept versus another calcineurin inhibitor, considered the key comparator in NHS Scotland. The submitting company's justification for the treatment's cost in relation to its health benefits was not sufficient and in addition, the company did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED
09.04.12 *SMC Report No. 775/12*	belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) *GlaxoSmithKline* *Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.*	NOT RECOMMENDED: belimumab (Benlysta®) is not recommended for use within NHS Scotland as an add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. Belimumab, in addition to standard of care, modestly improved disease control in patients with SLE in two phase III studies. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and, in addition, the submitting company did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED
09.07.07 *SMC Report No. 206/05* RESUBMISSION	bemiparin 25,000 IU/mL injection for sub-cutaneous administration (Zibor®) *Pan Quimica Farmaceutica, S.A.* *Treatment of established deep vein thrombosis, with or without pulmonary embolism, during the acute phase.*	NOT RECOMMENDED: bemiparin 25,000 IU/mL (Zibor®) is not recommended for use within NHS Scotland for the treatment of established deep vein thrombosis, with or without pulmonary embolism, during the acute phase. Greater numbers of patients had a reduction in thrombus size with bemiparin than unfractionated heparin, although bemiparin has not been compared with other low molecular weight heparins. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
10.10.05 *SMC Report No. 205/05*	bemiparin, 2500 IU in 0.2mL and 3500 IU in 0.2mL, injection for sub-cutaneous administration (Zibor®) *Amdipharm* *Prevention of clotting in the extracorporeal circuit during haemodialysis.*	NOT RECOMMENDED: bemiparin (Zibor®) is not recommended for use within NHS Scotland for the prevention of clotting in the extracorporeal circuit during haemodialysis. It showed similar efficacy to unfractionated heparin in preventing coagulation in the extracorporeal circuit but has not been compared with other low molecular weight heparins. No evidence of the cost effectiveness of bemiparin during haemodialysis has been presented by the manufacturer.	NOT RECOMMENDED
07.12.09 *SMC Report No. 204/05* 2ND RESUBMISSION	bemiparin 3500 IU in 0.2mL injection for sub-cutaneous administration (Zibor®) *Pan Quimica Farmaceutica, S.A.* *Prevention of thromboembolic events in patients undergoing orthopaedic surgery.*	Accepted for use: bemiparin (Zibor®) is accepted for use within NHS Scotland for the prevention of thromboembolic disease in patients undergoing orthopaedic surgery. Bemiparin was associated with a lower incidence of thromboembolic complications than unfractionated heparin and was non-inferior to another low molecular weight heparin.	'Not preferred' in Lothian as suitable alternatives exist. FC May 2011

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
10.10.05 *SMC Report No. 203/05*	bemiparin, 2500 IU in 0.2mL injection for sub-cutaneous administration (Zibor®) *Amdipharm* *Prevention of thromboembolic disease: general surgery.*	NOT RECOMMENDED: bemiparin (Zibor®) is not recommended for use within NHS Scotland for the prevention of thromboembolic disease in patients undergoing general surgery. In one small study neither bemiparin nor unfractionated heparin was associated with thromboembolic complications following abdominal surgery but major bleeding and wound haematoma were more common with unfractionated heparin. Bemiparin has not been evaluated in other general surgery settings or against other low molecular weight heparins. No evidence of the cost effectiveness of bemiparin during general surgery has been presented by the manufacturer.	NOT RECOMMENDED
09.07.07 *SMC Report No. 206/05* RESUBMISSION	bemiparin 25,000 IU/mL injection for sub-cutaneous administration (Zibor®) *Pan Quimica Farmaceutica, S.A.* *Treatment of established deep vein thrombosis, with or without pulmonary embolism, during the acute phase.*	NOT RECOMMENDED: bemiparin 25,000 IU/ml (Zibor®) is not recommended for use within NHS Scotland for the treatment of established deep vein thrombosis, with or without pulmonary embolism, during the acute phase. Greater numbers of patients had a reduction in thrombus size with bemiparin than unfractionated heparin, although bemiparin has not been compared with other low molecular weight heparins. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
11.04.11 *SMC Report No. 694/11*	bendamustine hydrochloride 25mg, 100mg powder for solution for infusion (Levact®) *Napp Pharmaceuticals Limited* *First-line treatment of chronic lymphocytic leukaemia (CLL) (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.*	Accepted for use; bendamustine hydrochloride (Levact®) is accepted for use within NHS Scotland. Indication under review: first-line treatment of chronic lymphocytic leukaemia (CLL) (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate. Bendamustine showed significantly improved response rates and progression free survival when compared with another alkylating agent in patients with previously untreated advanced CLL, although the patients studied may have been younger and fitter than those eligible to receive bendamustine in Scottish clinical practice.	Added to the Additional List. **Included** on the Lothian Joint Formulary for the indication in question. Until further evidence is provided, the use of bendamustine in combination with rituximab can be undertaken via non-formulary route. FC April 2012
11.04.11 *SMC Report No: 700/11* NON SUBMISSION	bendamustine 2.5mg/mL powder for concentrate for solution for infusion (Levact®) *Napp Pharmaceuticals Limited* *Treatment of multiple myeloma.*	NOT RECOMMENDED: bendamustine (Levact ®) is not recommended for use within NHS Scotland. Indication under review: for the front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.04.11 *SMC Report No: 701/11* NON SUBMISSION	bendamustine 2.5mg/mL powder for concentrate for solution for infusion (Levact®) *Napp Pharmaceuticals Limited* *Treatment of indolent non-Hodgkin's lymphomas.*	NOT RECOMMENDED: bendamustine (Levact ®) is not recommended for use within NHS Scotland. Indication under review: for the front line treatment of indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.08.10 *SMC Report No. 407/07* 2nd RESUBMISSION	betaine anhydrous oral powder (Cystadane®) *Orphan Europe (UK) Limited* *Adjunctive treatment of homocystinuria involving deficiencies or defects in cystathionine beta-synthase (CBS), 5,10-methylene-tetrahydrofolate reductase (MTHFR) or cobalamin cofactor metabolism (cbl).*	Restricted use; betaine anhydrous (Cystadane®) is accepted for restricted use within NHS Scotland. Indication under review: adjunctive treatment of homocystinuria involving deficiencies or defects in cystathionine beta-synthase (CBS), 5,10-methylene-tetrahydrofolate reductase (MTHFR) or cobalamin cofactor metabolism (cbl). SMC restriction: patients who are not responsive to vitamin B6 treatment. Limited clinical data confirmed the effectiveness of betaine anhydrous in homocystinuria, There remains some uncertainty about the cost-effectiveness of betaine anhydrous even in the restricted patient group described above, but given the orphan nature of the condition the economic case for use was accepted.	Added to the Additional List. FC August 2011
09.08.10 *SMC Report No. 622/10*	betamethasone valerate 2.25mg medicated plaster (Betesil®) *Genus Pharmaceuticals* *Treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides.*	NOT RECOMMENDED: betamethasone valerate medicated plaster (Betesil®) is not recommended for use within NHS Scotland. Indication under review: Treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Due to its particular pharmaceutical form, betamethasone medicated plaster is suitable for chronic plaque psoriasis localized in difficult to treat areas (e.g. knees, elbows and anterior face of the tibia on an area not greater than 5% of the body surface). In phase III studies in patients with mild to moderate plaque psoriasis, betamethasone medicated plaster was superior to non-occluded betamethasone cream, assessed using the psoriasis area and severity index score and psoriasis global assessment. However, the manufacturer did not submit a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.06.06 *SMC Report No. 221/05* RESUBMISSION Superseded by MTA 242 January 2012	bevacizumab 100mg/4mL and 400mg/16mL solution for intravenous infusion (Avastin®) *Roche* *First-line treatment of patients with metastatic carcinoma of the colon or rectum.*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with intravenous fluorouracil/folinic acid or intravenous fluorouracil/folinic acid/irinotecan for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Bevacizumab, in combination with standard regimens containing fluorouracil and folinic acid or fluorouracil, folinic acid and irinotecan, improved overall and disease-free survival times compared to these standard regimens. However, the economic case has not been demonstrated. MTA 242 Bevacizumab in combination with non-oxaliplatin (fluoropyrimide-based) chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.	NOT RECOMMENDED
09.07.07 *SMC Report No. 387/07* NON SUBMISSION	bevacizumab (Avastin®) *Roche Pharmaceuticals* *In combination with paclitaxel for first-line treatment of patients with metastatic breast cancer.*	NOT RECOMMENDED: bevacizumab (Avastin®) in combination with paclitaxel is not recommended for first-line treatment of patients with metastatic breast cancer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.12.07 *SMC Report No. 425/07* NON SUBMISSION	bevacizumab (Avastin®) *Roche Pharmaceuticals* *In addition to platinum-based chemotherapy, for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.*	NOT RECOMMENDED: bevacizumab (Avastin®) in addition to platinum-based chemotherapy, is not recommended for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.03.08 *SMC Report No. 459/08* NON SUBMISSION	bevacizumab (Avastin®) *Roche Pharmaceuticals* *For use in combination with interferon alfa-2a for the first line treatment of patients with advanced and/or metastatic renal cell cancer.*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with interferon alfa-2a for the first line treatment of patients with advanced and/or metastatic renal cell cancer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
09.06.08 *SMC Report No. 469/08*	bevacizumab, 100mg and 400mg vials (Avastin®) *Roche* *In combination with fluoropyrimidine-based chemotherapy for treatment of patients with metastatic carcinoma of the colon or rectum.*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with fluoropyrimidine-based chemotherapy for treatment of patients with metastatic carcinoma of the colon or rectum. In a randomised trial standard chemotherapy plus bevacizumab showed a small benefit over standard chemotherapy alone in terms of progression-free survival. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
14.05.12 *SMC Report No. 778/12*	bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) *Roche Products Ltd.* *In combination with capecitabine is indicated for first-line treatment of patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate.*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with capecitabine is indicated for first-line treatment of patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. In a double-blind, multicentre, randomised, placebo-controlled phase III study in patients with locally recurrent or metastatic breast cancer, treatment with bevacizumab plus capecitabine was associated with an extended median progression-free survival of 2.9 months compared with capecitabine monotherapy. However, there was no overall significant improvement in survival. The submitting company did not present a sufficiently robust economic analysis and, in addition, their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by the SMC.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.10.12 *SMC Report No. 806/12*	bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) *Roche Products Ltd* *In combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. In two phase lll studies, bevacizumab in combination with carboplatin and paclitaxel significantly increased progression free survival compared with carboplatin and paclitaxel alone in patients with advanced ovarian cancer. The submitting company's base case economic analysis was based on an unlicensed dose of the medicine and this is not within the SMC remit. For the sensitivity analysis using the licensed dose, the submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
11.03.13 *SMC Report No. 853/13*	bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) *Roche Products Ltd* *Bevacizumab, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelian ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents.*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelian ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents. A randomised double-blind, placebo-controlled, phase III study demonstrated a significant improvement in progression-free survival (PFS) in patients with platinum-sensitive recurrent ovarian cancer (ROC) treated with bevacizumab in combination with gemcitabine and carboplatin, compared with gemcitabine and carboplatin alone. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
08.11.02 *SMC Report No. 14/02*	bexarotene capsules (Targretin®) *Elan Pharma* *Second line treatment for patients with advanced (stages IIb or III) cutaneous T-cell lymphoma.*	Restricted use: bexarotene capsules (Targretin®) is recommended as a second line treatment for patients with advanced (stages IIb or III) cutaneous T-cell lymphoma. Bexarotene treatment should normally be initiated and supervised by haematologists, dermatologists or oncologists and used for patients who have proved refractory both to local skin directed therapy and to at least one systemic treatment.	Added to the Additional List as a second line treatment for patients with cutaneous T-cell lymphoma (stages IIb or III). FC May 2003
09.08.02 *SMC Report No. 07/02*	bimatoprost (Lumigan®) *Allergan Ltd* *Glaucoma & ocular hypertension.*	Accepted for use: bimatoprost (Lumigan®) is recommended for general use within the NHS in Scotland as adjunctive therapy to beta-blockers or as monotherapy in patients insufficiently responsive to, intolerant of or contraindicated to first-line therapy. It should be used under the direction of an ophthalmologist.	Added to the Additional List. FC February 2005
09.10.06 *SMC Report No. 312/06* PRODUCT UPDATE (abbreviated submission)	bimatoprost 0.03%, timolol 0.5% eye drops (Ganfort®) *Allergan Ltd* *Reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues and for whom this combination offers an appropriate choice.*	Accepted for use: bimatoprost 0.03%, timolol 0.5% eye drops (Ganfort®) are accepted for use in NHS Scotland for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension, who are insufficiently responsive to topical beta-blockers or prostaglandin analogues and for whom this combination offers an appropriate choice.	'Not preferred' as suitable alternatives exist. FC August 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.03.13 *SMC Report No. 839/13* PRODUCT UPDATE (abbreviated submission)	bimatoprost 0.3mg/mL single-dose eye drops (Lumigan UD®) *Allergan Ltd* *Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers).*	Restricted use: bimatoprost 0.3mg/mL preservative-free eye drops (Lumigan UD®) are accepted for restricted use within NHS Scotland for reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers). SMC restriction: to use in patients who have proven sensitivity to the preservative benzalkonium chloride. SMC has previously accepted preserved bimatoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation with preservative.	**Not included** in the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. The current LJF choice is travoprost. FC March 2013
07.10.13 *SMC Report No. 906/13* PRODUCT UPDATE (abbreviated submission)	bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eye-drops (Ganfort® Unit Dose Preservative Free) *Allergan Ltd* *For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.*	Restricted use: bimatoprost plus timolol preservative-free eye-drops (Ganfort® Unit Dose Preservative Free) are accepted for restricted use within NHS Scotland for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. SMC restriction: to use in patients who have proven sensitivity to preservatives. SMC has previously accepted preserved bimatoprost plus timolol eye-drops for use in NHS Scotland. This preparation is more expensive than the equivalent multi-dose eye drop preparation with preservative.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is travoprost or latanoprost preservative-free single dose eye drops for those with proven sensitivity to preservatives. Timolol is available as a preservative free preparation. FC October 2013
09.05.03 *SMC Report No. 06/02* RESUBMISSION	biphasic insulin aspart (NovoMix 30®) *Novo Nordisk Ltd* *Treatment of patients with diabetes mellitus.*	Accepted for use: biphasic insulin aspart (NovoMix 30®) is recommended for general use within NHS Scotland. In trials of 12 weeks duration, biphasic insulin aspart has demonstrated similar effects on HbA1c levels to biphasic human insulin 30 and biphasic insulin lispro Mix 25. Biphasic insulin aspart 30 has demonstrated similar effects to its competitor insulins and therefore is an effective treatment for diabetes at broadly similar costs.	Approved for use - added to the Formulary, for initiation in secondary care. FC September 2003
07.03.05 *SMC Report No. 156/05*	bivalirudin 250mg for injection or infusion (Angiox®) *Nycomed UK Ltd* *Percutaneous coronary intervention.*	Restricted use: bivalirudin (Angiox®) is accepted for restricted use within NHS Scotland as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI), including percutaneous transluminal coronary angioplasty (PTCA) procedures like angioplasty and balloon angioplasty and PTCA with stenting. It is restricted to patients who would have been considered for treatment with unfractionated heparin in combination with a glycoprotein IIb/IIIa antagonist. In these patients bivalirudin monotherapy may be a suitable alternative. It should not be used as an alternative to unfractionated heparin alone.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
08.12.08 *SMC Report No. 516/08*	bivalirudin, 250mg powder for concentrate for solution for injection or infusion (Angiox®) *The Medicines Company UK Ltd* *Treatment of adult patients with acute coronary syndromes (unstable angina/non-ST segment elevation myocardial infarction) planned for urgent or early intervention.*	Restricted use: bivalirudin (Angiox®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with acute coronary syndromes (unstable angina/non-ST segment elevation myocardial infarction) planned for urgent or early intervention. It is restricted to use in patients who would otherwise have been considered for heparin in combination with a glycoprotein IIb/IIIa antagonist. In these patients bivalirudin monotherapy may be a suitable alternative. It should not be used as an alternative to heparin alone. Bivalirudin should be administered with aspirin and clopidogrel. Bivalirudin showed a reduced risk of bleeding compared to a heparin-based anticoagulant strategy in patients with moderate and high risk acute coronary syndromes undergoing early invasive management.	'Not preferred' in Lothian as suitable alternatives exist. FC November 2009

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.08.11 *SMC Report No: 730/11* NONSUBMISSION	bilastine (Ilaxten®) *A Menarini PharmaU.K. S.R.L.* *Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.*	NOT RECOMMENDED: bilastine (Ilaxten®) is not recommended for use within NHS Scotland. Indication under review: symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.09.10 *SMC Report No. 638/10*	bivalirudin 250mg powder for concentrate for solution for injection or infusion (Angiox®) *The Medicines Company UK Ltd* *As an anticoagulant in adult patients undergoing percutaneous coronary intervention (PCI), including patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI. Bivalirudin should be administered with aspirin and clopidogrel.*	Restricted use: bivalirudin (Angiox®) is accepted for restricted use within NHS Scotland. Indication under review: as an anticoagulant in adult patients undergoing percutaneous coronary intervention (PCI), including patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI. Bivalirudin should be administered with aspirin and clopidogrel. Restriction: patients who would have been considered for treatment with heparin in combination with a glycoprotein IIb/IIIa inhibitor. It should not be used as an alternative to heparin alone. In patients with STEMI undergoing PCI, bivalirudin, compared with heparin plus a glycoprotein IIb/IIIa inhibitor, was associated with significantly lower rates of major bleeding, cardiac death and thrombocytopenia.	'Not preferred' in Lothian as suitable alternatives exist. FC May 2011
10.10.11 *SMC Report No. 722/11*	boceprevir 200mg capsule (Victrelis®) Treatment experienced patients *Merck, Sharpe and Dohme Ltd* *Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy.*	Accepted for use: boceprevir (Victrelis®) is accepted for use within NHS Scotland. Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who have failed previous therapy. In the pivotal phase III randomised study, addition of boceprevir to current standard therapy in patients with HCV, who had failed previous therapy, increased the proportion of patients who achieved a sustained virologic response.	Added to the Additional List, for Specialist use only. FC March 2012
10.10.11 *SMC Report No. 723/11*	boceprevir 200mg capsule (Victrelis®) Treatment naïve patients *Merck Sharpe and Dohme Ltd* *Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon and ribavirin, in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy.*	Accepted for use: boceprevir (Victrelis®) is accepted for use within NHS Scotland. Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon and ribavirin, in adult patients with compensated liver disease who are previously untreated. In the pivotal, phase III randomised study, addition of boceprevir to current standard therapy in patients with HCV who were previously untreated increased the proportion of patients with HCV who achieved a sustained virologic response.	Added to the Additional List, for Specialist use only. FC March 2012
11.10.04 *SMC Report No. 126/04*	bortezomib (Velcade®) *Ortho Biotech* *Multiple myeloma.*	Accepted for use: bortezomib (Velcade®) is accepted for use within NHS Scotland for the treatment of patients with multiple myeloma who have received at least two prior therapies, have demonstrated disease progression on the last therapy and who are refractory to alternative licensed treatments for this stage of the disease. Bortezomib produced a disease response in approximately one third of these patients in an open-label uncontrolled study. Any other use of bortezomib should only take place within the context of a controlled study. The manufacturers are encouraged to mount an observational study in collaboration with haemato-oncologists to gain more information on the benefits and risks of this therapy.	Added to the Additional List, for Specialist use only. Bortezomib may be appropriate for patients who have relapsed after thalidomide treatment according to agreed protocol. FC November 2004

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
09.11.09 *SMC Report No. 302/06* 2ND RESUBMISSION Patient Access Scheme	bortezomib 3.5mg powder for intravenous injection (Velcade®) *Ortho Biotech* *As mono-therapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation.*	Accepted for use: bortezomib (Velcade®) is accepted for use within NHS Scotland as mono-therapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation. Bortezomib, compared to high dose dexamethasone, prolonged time to disease progression and improved survival in patients who had progressive multiple myeloma despite previous treatment with one to three lines of therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bortezomib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist use only. FC December 2011
10.12.12 *SMC Report No. 822/12* PRODUCT UPDATE (abbreviated submission) Patient Access Scheme	bortezomib (Velcade®) 3.5mg powder for subcutaneous injection *Janssen-Cilag Ltd* *In combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.*	Accepted for use: bortezomib subcutaneous injection (Velcade®) is accepted for use within NHS Scotland in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant. As monotherapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation. The subcutaneous formulation of bortezomib has been shown to be clinically non-inferior to the intravenous formulation and is the same price. SMC previously accepted bortezomib intravenous injection as monotherapy in the treatment of multiple myeloma when the benefits of a Patient Access Scheme (PAS) were taken into account. The Patient Access Scheme Assessment Group (PASAG) has confirmed that this response-based PAS also applies to the subcutaneous formulation when used in this setting. This SMC advice is therefore contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. Bortezomib intravenous injection has also been accepted for use in NHS Scotland in specific circumstances in the first line treatment of multiple myeloma as Healthcare Improvement Scotland has endorsed NICE MTA No 228 (Bortezomib and thalidomide for the first line treatment of multiple myeloma) in July 2011. The PAS does not apply to the use of bortezomib in this setting.	**Included** on the Additional List, for Specialist Use only, for the indication included in PAS. FC December 2012
13.01.14 *SMC Report No. 927/13*	bortezomib 3.5mg powder for solution for injection (Velcade®) *Janssen-Cilag Ltd* *In combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.*	Restricted use: bortezomib (Velcade®) is accepted for restricted use within NHS Scotland in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation. SMC restriction: use as triple therapy in combination with dexamethasone and thalidomide. Bortezomib, used in combination with dexamethasone and thalidomide for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation improved response rates compared with a dual combination regimen.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC February 2014

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.11.08 *SMC Report No. 523/08* NON SUBMISSION	bosentan 62.5mg, 125mg film-coated tablets (Tracleer®) *Actelion Pharmaceuticals UK Ltd* *The treatment of pulmonary arterial hypertension (PAH) WHO functional class II.*	NOT RECOMMENDED: bosentan (Traceleer®), is not recommended for use within NHS Scotland for the treatment of pulmonary arterial hypertension (PAH) WHO functional class II. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
09.06.08 *SMC Report No. 485/08* NON SUBMISSION	bosentan 62.5mg, 125mg film coated tablets (Tracleer®) *Actelion Pharmaceuticals UK* *To reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease.*	NOT RECOMMENDED: bosentan (Tracleer®) is not recommended for use within NHSScotland to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.03.03 *SMC Report No. 32/03*	bosentan (Tracleer®) *Actelion Pharmaceuticals UK Ltd* *Grade III pulmonary arterial hypertension.*	Restricted use: bosentan (Tracleer®) is recommended for restricted use within NHS Scotland. This medicine was approved by EMEA under the accelerated licensing process, thus evidence of its efficacy is limited. Bosentan may be a potentially useful alternative to epoprostenol for patients with Grade III pulmonary arterial hypertension. It offers major advantages over epoprostenol in its ease of administration. However, there are currently scant data on the effectiveness of these products on patient survival. The hepatotoxicity and teratogenicity of bosentan have led the EMEA to recommend post-marketing surveillance and the company operates this as a controlled release programme. The cost effectiveness of bosentan is impossible to estimate at present, and may be low. Bosentan should only be prescribed for patients who are treated in specialist centres run by physicians experienced in the management of these disorders.	Approved for use - patients receive prescriptions from the Scottish Pulmonary Vascular Unit in Glasgow. FC March 2003
11.11.13 *SMC Report No. 910/13*	bosutinib 100mg, 500mg film-coated tablets (Bosulif®) *Pfizer Ltd* *Treatment of adult patients with chronic phase, accelerated phase, and blast phase Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.*	NOT RECOMMENDED: bosutinib (Bosulif®) is not recommended for use within NHS Scotland for the treatment of adult patients with chronic phase, accelerated phase, and blast phase Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. Evidence of efficacy for the indication under review comes from a subgroup of 52 patients who represent "unmet medical need" in the pivotal study, in which the full population included 546 patients with chronic, accelerated and blast phase imatinib pre-treated Ph+ CML. The submitting company did not present a sufficiently robust clinical and economic analysis and in addition their justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
17.01.11 *SMC Report No. 679/11* NON SUBMISSION	botulinum toxin type A (Azzalure®) *Galderma* *Temporary improvement in the appearance of moderate to severe glabellar lines (vertical "frown" lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient.*	NOT RECOMMENDED: botulinum toxin type A (Azzalure®) is not recommended for use within NHS Scotland. Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical "frown" lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication due to its cosmetic nature. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED:

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
17.01.11 *SMC Report No. 680/11* NON SUBMISSION	botulinum toxin Type A (Vistabel®) *Allergan* *Temporary improvement in the appearance of moderate to severe glabellar lines (vertical "frown" lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient.*	NOT RECOMMENDED: botulinum toxin Type A (Vistabel®) is not recommended for use within NHS Scotland. Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical "frown" lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication due to its cosmetic nature. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.03.11 *SMC Report No. 695/11* NON SUBMISSION	botulinum toxin type A (Bocouture®) *Merz Pharma* *Temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at frown, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.*	NOT RECOMMENDED: botulinum toxin type a (Bocouture ®) is not recommended for use within NHS Scotland. Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at frown, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication due to its cosmetic nature. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.04.13 *SMC Report No. 692/11* RESUBMISSION	botulinum toxin type A, 50 unit, 100 unit and 200 unit powder for solution for injection (Botox®) *Allergan Ltd.* *The prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).*	NOT RECOMMENDED: botulinum toxin type A (Botox®) is not recommended for use within NHS Scotland for the treatment of the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). In pooled analysis of the two pivotal phase III studies, botulinum toxin type A significantly reduced the frequency of headache days compared with placebo. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
10.10.11 *SMC Report No. 731/11* PRODUCT UPDATE (abbreviated submission)	botulinum toxin type A, 50 and 100 LD_{50} units powder for solution for injection (Xeomin®) *Merz Pharma UK Ltd* *Post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults.*	Accepted for use: botulinum toxin type A (Xeomin®) is accepted for use within NHS Scotland. Post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults. In patients for whom botulinum toxin, type A is an appropriate choice of therapy, this offers an alternative formulation to the comparator product containing conventional botulinum toxin, type A complex.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.10.13 *SMC Report No. 916/13*	botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®) *Allergan Ltd* *Management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required.*	Accepted for use: botulinum toxin type A (Botox®) is accepted for use within NHS Scotland for management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required. In two phase III, double-blind, placebo-controlled studies, in which all patients received best supportive care, botulinum toxin type A 200 units (licensed dose) was significantly superior to placebo for mean reduction in weekly urinary incontinence episodes, from baseline to week six. There are currently limited data on re-treatment.	**Not included** on the LJF, pending protocol. FC October 2013
07.07.14 *SMC Report No. 931/13*	botulinum toxin type A powder for solution for injection (BOTOX®) *Allergan Ltd* *The management of bladder dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency.*	Restricted use: botulinum toxin type A (BOTOX®) is accepted for restricted use within NHS Scotland for the management of bladder dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency. SMC restriction: Patients who have failed appropriate oral treatment options. In two phase III double-blind studies, botulinum toxin type A (BOTOX®) significantly reduced the mean daily number of urinary incontinence episodes compared with placebo.	Formulary classification not yet decided – waiting for information from clinician.
07.07.14 SMC Report No. 986/14 NON SUBMISSION	botulinum toxin type A 50, 100 and 200 units (Botox®) *Allergan Ltd* *Focal lower limb spasticity, including the treatment of ankle disability due to lower limb spasticity associated with stroke in adults.*	NOT RECOMMENDED: botulinum toxin type A (Botox®) is not recommended for use within NHS Scotland for focal lower limb spasticity, including the treatment of ankle disability due to lower limb spasticity associated with stroke in adults The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
14.01.13 SMC Report No. 845/12 NON SUBMISSION	brentuximab vedotin (Adcetris®) 50 mg powder for concentrate for solution for infusion *Takeda UK Ltd* *Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):* *1. following autologous stem cell transplant (ASCT) or* *2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option* *and* *treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).*	NOT RECOMMENDED: brentuximab vedotin (Adcetris®) is not recommended for use within NHS Scotland for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
12.09.05 *SMC Report No. 196/05* PRODUCT UPDATE (abbreviated submission)	brimonidine tartrate/timolol (Combigan®) eye drops *Allergan Ltd* *Reduction of intra-ocular pressure.*	Accepted for use: brimonidine/timolol (Combigan®) eye drops are accepted for use in NHS Scotland for the reduction of intra-ocular pressure in patients, with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers alone and for whom brimonidine is an appropriate choice of adjuvant therapy. The combination product may be associated with a modest decrease in cost compared with the individual components and allows patients to administer fewer drops.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
14.04.09 *SMC Report No. 546/09* PRODUCT UPDATE (abbreviated submission)	brinzolamide 10mg/mL eye drops (Azopt®) *Alcon Laboratories (UK) Limited* *Treatment of elevated intraocular pressure in ocular hypertension and open-angle glaucoma as monotherapy in patients unresponsive to beta-blockers or in patients in whom beta-blockers are contraindicated, or as adjunctive therapy to beta-blockers or prostaglandin analogues.*	Accpeted for use: brinzolamide (Azopt®) eye drops are accepted for use within NHS Scotland to decrease elevated intraocular pressure in ocular hypertension and open-angle glaucoma as monotherapy in patients unresponsive to beta-blockers or in patients in whom beta-blockers are contraindicated, or as adjunctive therapy to beta-blockers or prostaglandin analogues. This abbreviated submission relates to a licence extension to cover use of brinzolamide with prostaglandin analogues. For patients in whom brinzolamide is an appropriate choice of therapy, this licence extension is not associated with a price increase and is not expected to increase drug usage.	Added to the LJF as first choice. FC July 2010
07.09.09 *SMC Report No. 568/09* PRODUCT UPDATE (abbreviated submission)	brinzolamide/timolol eye drops, suspension (Azarga®) *Alcon Laboratories (UK) Ltd* *Treatment of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.*	Accepted for use: brinzolamide/timolol eye drops, suspension (Azarga®) are accepted for use within NHS Scotland for the decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. The combination product allows patients to administer fewer drops at a modestly increased cost over separate administration of the constituents.	Added to the LJF as a prescribing note. FC July 2010
10.10.11 SMC Report No. 740/11 NON SUBMISSION	bromfenac (Yellox ®) 0.9 mg/mL eye drops solution *Bausch & Lomb* *Treatment of postoperative ocular inflammation following cataract extraction in adults.*	NOT RECOMMENDED: bromfenac (Yellox ®) eye drops are not recommended for use within NHS Scotland treatment of postoperative ocular inflammation following cataract extraction in adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.10.07 *SMC Report No. 409/07* PRODUCT UPDATE (abbreviated submission)	budesonide 2mg rectal foam (Budenofalk®) *Dr Falk Pharma UK Ltd* *Treatment of active ulcerative colitis that is limited to the rectum and the sigmoid colon.*	Accepted for use: budesonide rectal foam (Budenofalk®) is accepted for use within NHS Scotland for the treatment of active ulcerative colitis that is limited to the rectum and the sigmoid colon. It should be used in patients for whom rectally administered budesonide is an appropriate choice of treatment. It costs less than equivalent doses of the other rectal formulation of budesonide.	'Not preferred' as suitable alternatives exist. FC October 2007

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.09.06 *SMC Report No. 306/06* PRODUCT UPDATE (abbreviated submission)	budesonide 200micrograms (Novolizer®) inhaler *Meda Pharmaceuticals Ltd* *Treatment of persistent asthma in adults and children over 6 years of age.*	Accepted for use: budesonide (Novolizer®) inhaler is accepted for use within NHS Scotland for the treatment of persistent asthma in adults and children over 6 years of age. Budesonide (Novolizer®) inhaler offers an alternative to existing dry powder inhaled formulations of budesonide at a similar cost.	New formulation of a drug already included in the Formulary. FC October 2007
13.03.06 *SMC Report No. 241/06* PRODUCT UPDATE (abbreviated submission)	budesonide inhaler 100micrograms, 200micrograms, 400micrograms (Easyhaler® Budesonide) *Ranbaxy (UK) Ltd* *Treatment of mild, moderate or severe persistent asthma in adults and children over 6 years of age.*	Accepted for use: budesonide inhaler (Easyhaler® Budesonide) is accepted for use within NHS Scotland for the treatment of mild, moderate or severe persistent asthma in adults and children over 6 years of age. Easyhaler® Budesonide offers an alternative to existing dry powder inhaled formulations of budesonide at a reduced cost.	New formulation of a drug already included in the Formulary.
14.04.09 *SMC Report No. 536/09* PRODUCT UPDATE (abbreviated submission)	budesonide CFC-free inhaler 100 micrograms and 200 micrograms per actuation (Pulmicort®) *AstraZeneca UK Ltd* *Treatment of asthma.*	Accepted for use: budesonide CFC-free inhaler (Pulmicort®) is accepted for use in NHS Scotland for the treatment of asthma. Budesonide CFC-free inhaler (Pulmicort®) (hydrofluoroalkanes [HFA] pressurised metered dose inhaler [pMDI]) replaces the equivalent CFC-containing pMDI formulations at a similar cost per microgram.	New formulation of a drug already included in the Formulary. FC April 2009
14.01.13 *SMC Report No. 828/12*	budesonide 3mg gastro-resistant capsule (Budenofalk®) *Dr Falk Pharma* *Symptomatic relief of chronic diarrhoea due to collagenous colitis.*	Accepted for use: budesonide gastro-resistant capsule (Budenofalk®) is accepted for use within NHS Scotland for symptomatic relief of chronic diarrhoea due to collagenous colitis. budesonide (Budenofalk®) provides symptomatic improvement of diarrhoea associated with collagenous colitis compared with placebo.	**Included** on the LJF as a first choice drug, for the indication in question. FC August 2013
14.01.13 *SMC Report No. 831/12* PRODUCT UPDATE (abbreviated submission)	budesonide 9mg gastro-resistant granules (Budenofalk®) *Dr Falk Pharma UK Ltd* *Induction of remission in patients with active collagenous colitis.*	Accepted for use: budesonide 9mg gastro-resistant granules (Budenofalk®) is accepted for use within NHS Scotland for the induction of remission in patients with active collagenous colitis. Budesonide gastro-resistant granules provides a once daily alternative to budesonide gastro-resistant 3mg capsules (which are given three times daily) at no additional cost. The granules may have advantages for patients who have difficulty swallowing.	**Included** on the LJF as a first choice drug, for the indication in question. FC August 2013
09.06.14 *SMC Report No. 970/14* PRODUCT UPDATE (abbreviated submission)	budesonide 9mg gastro-resistant granules (Budenofalk®) *Dr Falk Pharma UK Limited* *Induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon.*	Accepted for use: budesonide gastro-resistant granules (Budenofalk®) is accepted for use within NHS Scotland for induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon. Budesonide gastro-resistant granules provide a once daily alternative to budesonide gastro-resistant 3mg capsules three times daily at no additional cost. The granules may have advantages for patients who have difficulty swallowing.	**Included** on the Additional List, for Specialist Initiation only, for the indication in question. FC May 2014

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
11.06.07 *SMC Report No. 362/07*	budesonide/formoterol 100/6, 200/6 turbohaler (Symbicort® SMART®) *Astra Zeneca UK Limited* *Regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting beta$_2$-agonist) is appropriate; Symbicort® is taken as regular maintenance treatment and as needed in response to symptoms.*	Accepted for use: budesonide/formoterol turbohaler (Symbicort® SMART®) is accepted for use within NHS Scotland, in adults, for the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting beta2-agonist) is appropriate; Symbicort® is taken as regular maintenance treatment and as needed in response to symptoms. In patients using inhaled budesonide/formoterol as preventer therapy, use of the same inhaler for reliever therapy is associated with a longer time to first severe exacerbation than use of comparator reliever regimens. In addition, some patients may be able to reduce the dose of preventer therapy.	'Not preferred' as suitable alternatives exist. FC December 2007
10.05.04 *SMC Report No. 97/04*	budesonide/formoterol inhaler (Symbicort Turbohaler®) *AstraZeneca UK Ltd* *Severe COPD.*	Accepted for use: budesonide/formoterol inhaler (Symbicort Turbohaler®) is accepted for use within NHS Scotland for the symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. It is the second of two long-acting β_2-agonist/corticosteroid combination inhaler preparations considered by SMC and licensed for the symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD). The individual components have been available for many years and the combination product offers ease of administration and additional convenience. The combination appears to improve lung function to a greater extent than either of the individual constituents given alone. Comparative data with other combination products are limited at the present time.	Added to the Formulary. Symbicort® and Seretide® are first choice inhaled combination products (containing corticosteroids and long-acting β_2-agonist bronchodilator) in the LJF. FC November 2004
12.03.12 *SMC Report No. 761/12* PRODUCT UPDATE (abbreviated submission	bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) *Goldshield Pharmaceuticals Ltd* *Epidural analgesia to relieve pain during labour and to control post operative pain.*	Accepted for use: bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) is accepted for use in NHS Scotland as epidural analgesia to relieve pain during labour and to control post operative pain. For patients in whom the combination of bupivacaine and fentanyl is an appropriate choice of therapy, Bufyl® provides two fixed-dose, pre-mixed preparations.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. FC November 2013
13.09.04 *SMC Report No. 116/04*	buprenorphine (Transtec®) patch *Napp Pharmaceuticals* *Moderate to severe cancer pain and severe pain.*	NOT RECOMMENDED: buprenorphine (Transtec®) patch is not recommended for use within NHS Scotland for the treatment of moderate to severe cancer pain and severe pain that does not respond to non-opioid analgesics. No comparative data have been provided with alternative transdermal or oral opioid preparations. The case for buprenorphine patches as a cost-minimising option when compared to the other transdermal opioid preparation marketed in the UK was not demonstrated. The licence holder has indicated their decision to resubmit.	NOT RECOMMENDED
12.01.09 *SMC Report No. 234/06* RESUBMISSION	buprenorphine transdermal patches 5, 10 and 20micrograms/hour new 7-day formulation (BuTrans®) *Napp Pharmaceuticals Ltd* *Treatment of severe opioid responsive pain conditions which are not adequately responding to non-opioid analgesics.*	NOT RECOMMENDED: buprenorphine transdermal patches (Butrans®) are not recommended for use within NHS Scotland for the treatment of severe opioid responsive pain conditions, which are not adequately responding to non-opioid analgesics. In the patient population considered in this submission, severe osteoarthritis pain in elderly patients whose pain is not adequately controlled by non-opioid analgesics, or for whom other analgesics are not suitable, buprenorphine transdermal 7-day patch was superior to placebo and similar in efficacy to comparator agents. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by the SMC.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
12.03.07 *SMC Report No. 355/07*	buprenorphine/naloxone 2mg/0.5mg, 8/2mg sublingual tablet (Suboxone®) *Schering Plough* *Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment.*	Restricted use: buprenorphine/naloxone (Suboxone®) is accepted for restricted use within NHS Scotland for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. In the pivotal trial buprenorphine/naloxone was superior to placebo and had similar efficacy and safety to buprenorphine. There are currently no published trials comparing buprenorphine/naloxone with methadone. Buprenorphine/naloxone is restricted to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.	Added to the Additional List. FC would support the further development of a SCP. FC November 2011 See also the webtable of detailing approved unlicensed and off-lable indications.
15.01.07 *SMC Report No. 337/06*	busulfan, 6mg/mL, intravenous (Busilvex®) *Pierre Fabre Ltd* *As part of a combination regimen for conditioning treatment prior to conventional haematopoietic progenitor cell transplantation (HPCT) in paediatric and adult patients.*	Accepted for use: busulfan for intravenous infusion (Busilvex®) is accepted for use within NHS Scotland as part of a combination regimen for conditioning treatment prior to conventional haematopoietic progenitor cell transplantation (HPCT) in paediatric and adult patients. The intravenous preparation offers advantages to patients over the oral formulation in terms of convenience of administration and predictability of blood levels. In adults it should be followed by cyclophosphamide (BuCy2) and in children it should be followed by cyclophosphamide (BuCy4) or by melphalan (BuMel).	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC June 2008
07.11.11 *SMC Report No. 735/11*	cabazitaxel, 60mg concentrate and solvent for solution for infusion (Jevtana®) *Sanofi-Aventis* *In combination with prednisone or prednisolone, cabazitaxel is licensed for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.*	NOT RECOMMENDED: cabazitaxel solution for infusion (Jevtana®) is not recommended for use within NHS Scotland in combination with prednisone or prednisolone, cabazitaxel is licensed for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. In an open-label, multicentre, randomised, controlled phase III study in patients with metastatic hormone-refractory prostate cancer, treatment with cabazitaxel plus prednisone or prednisolone was associated with an extended median overall survival of 2.4 months compared with an alternative chemotherapy regimen. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
11.05.09 *SMC Report No. 550/09*	caffeine base 5mg/mL solution for injection *Viridian Pharma Ltd* *Treatment of apnoea of prematurity.*	Restricted use: caffeine base 5mg/mL solution for injection is accepted for restricted use within NHS Scotland for the treatment of apnoea of prematurity. Short-term studies have demonstrated the efficacy of caffeine on apnoeic episodes and one longer-term study has shown reduction in disabilities relevant to these infants. It should be restricted to use on the advice of specialists in neonatal paediatrics. Prescribers should note that, although the SPC describes this product in terms of caffeine base (5mg/mL), the neonatal formulary and the British National Formulary for Children currently recommend prescribing the dose as caffeine citrate (equivalent to 10mg/mL).	Added to the Additional List, for Specialist Use only. FC December 2009

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.09.13 *SMC Report No. 814/12* Patient Access Scheme	caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®) *Chiesi Limited* *Treatment of primary apnoea of premature newborns.*	Accepted for use: caffeine citrate (Peyona®) is accepted for use within NHS Scotland for the treatment of primary apnoea of premature newborns. In premature infants with apnoea of prematurity, caffeine citrate significantly reduced apnoeic episodes compared with placebo. A long-term placebo-controlled study demonstrated a reduced risk of disabilities relevant to these infants. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of caffeine citrate (Peyona®). This SMC advice is contingent upon the continuing availability of the PAS or an equivalent or lower list price in NHS Scotland. This replaces advice previously issued by the Scottish Medicines Consortium for caffeine citrate (Peyona®) in September 2012 following a non-submission.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC January 2014
12.12.05 *SMC Report No. 09/02* RESUBMISSION	calcipotriol and betamethasone dipropionate ointment (Dovobet®) *Leo Pharma* *Initial topical treatment of stable plaque psoriasis.*	Restricted use: calcipotriol/betamethasone dipropionate ointment (Dovobet®) is accepted for restricted use within NHS Scotland for the initial topical treatment of stable plaque psoriasis. Short term comparisons have shown that the combination is more effective than either component as monotherapy and that it is cost effective compared to alternative therapies. Its use is restricted to physicians experienced in treating inflammatory skin disease. Dovobet® contains a potent steroid, the use of which carries risks of destabilising psoriasis and side effects from prolonged use. The duration of treatment should not exceed four weeks.	Added to the LJF as a prescribing note. Treatment restricted to 4 weeks maximum, treatment by Specialists only. Repeat courses should not be used. FC December 2007
10.08.09 *SMC Report No. 559/09*	calcipotriol and betamethasone dipropionate, 50 micrograms/g + 500 microgram/g gel (Xamiol®) *LEO Pharma* *Topical treatment of scalp psoriasis*	Accepted for use: calcipotriol and betamethasone dipropionate scalp gel, (Xamiol®) is accepted for use within NHS Scotland for the topical treatment of scalp psoriasis. Short-term comparisons have shown that the combination is more effective than either component used as monotherapy.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010
09.05.03 *SMC Report No. 43/03*	calcitriol 3micrograms/g ointment (Silkis®) *Galderma (UK) Ltd* *Treatment of mild to moderate plaque psoriasis in adults.*	Accepted for use: calcitriol 3micrograms/g ointment (Silkis®) is recommended for general use within NHS Scotland. Limited data indicate comparable efficacy and similar or better tolerability of calcitriol compared to existing topical vitamin D analogues in the treatment of mild to moderate plaque psoriasis in adults. As calcitriol ointment is a substitute for existing medicines that have similar or increased costs, it is assumed that the net budget impact to the NHS will be minimal.	Added to the Formulary as first choice drug because it is thought to be better tolerated than current therapies. A replacement for topical calcipotriol (Dovonex®) for the treatment of mild to moderate plaque psoriasis. FC January 2004
08.08.11 *SMC Report No: 718/11* PRODUCT UPDATE (abbreviated submission)	calcium carbonate equivalent to 500mg calcium, cholecalciferol (vitamin D3) 800 IU (20 microgram) tablets (Kalcipos-D 500mg/800 IU chewable tablets®) *Meda Pharmaceuticals Ltd* *Indication see next box.*	Accepted for use: calcium carbonate and cholecalciferol (Kalcipos-D®) is accepted for use within NHS Scotland. Indications under review: •Prevention and treatment of calcium and vitamin D deficiency in the elderly. •Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency. This is a new combination product with a different ratio of calcium to cholecalciferol than alternative combination preparations. It is a similar price to an alternative product containing 800IU of cholecalciferol per tablet but is more expensive than some other calcium and cholecalciferol combinations. Any overall budget impact is likely to be small.	'Not preferred' as suitable alternatives exist. FC August 2011

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
08.02.10 *SMC Report No. 601/10* PRODUCT UPDATE (abbreviated submission)	calcium acetate 667mg hard capsules (PhosLo®) *Fresenius Medical Care (UK) Ltd* *Prevention/treatment of hyperphosphataemia in patients with advanced renal failure on dialysis.*	Accepted for use: calcium acetate (PhosLo®) is accepted for use in NHS Scotland for prevention/treatment of hyperphosphataemia in patients with advanced renal failure on dialysis. For patients in whom calcium acetate is an appropriate phosphate binding agent this product is available at a cost per unit of calcium equivalent to that of an existing preparation.	Added to the Formulary. FC March 2010
11.04.11 *SMC Report No 693/11*	calcium acetate 435mg/magnesium carbonate 235mg tablet (Osvaren®) *Fresenius Medical Care* *Treatment of hyperphosphataemia associated with chronic renal insufficiency in patients undergoing dialysis (haemodialysis, peritoneal dialysis).*	NOT RECOMMENDED: calcium acetate 435mg/magnesium carbonate 235mg tablet (Osvaren®) is not recommended for use within NHS Scotland. Indication under review: treatment of hyperphosphataemia associated with chronic renal insufficiency in patients undergoing dialysis (haemodialysis, peritoneal dialysis). The combined preparation of calcium acetate/magnesium carbonate has been shown to reduce hyperphosphataemia associated with chronic renal disease. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
13.10.03 *SMC Report No. 72/03* PRODUCT UPDATE (abbreviated submission)	calcium phosphate, colecalciferol (Calfovit D3®) *Trinity Pharmaceuticals* *Correction of calcium and Vitamin D deficiency in the elderly.*	Accepted for use: New combination product for correction of calcium and Vitamin D deficiency in the elderly. This product is a once-daily formulation of calcium phosphate and colecalciferol and is an appropriate less expensive alternative to existing treatments.	Approved for use - added to the Formulary as second choice after Adcal-D_3®. Calfovit D3® is available as powder sachets and it may be useful for patients who have difficulty chewing tablets. FC April 2005
12.08.13 *SMC Report No. 890/13* PRODUCT UPDATE (abbreviated submission)	calcium polystyrene sulphonate powder for oral/rectal suspension (Sorbisterit®) *Stanningley Pharma Ltd* *Treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment.*	Accepted for use: calcium polystyrene sulphonate powder (Sorbisterit®) is accepted for use within NHS Scotland for the treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment. Sorbisterit® provides an alternative to the existing proprietary product at a lower cost. The dose of Sorbisterit® and the existing proprietary product differ as the strength of the active ingredient varies slightly.	**Included** on the Additional List, Specialist Use only for the indication in question. FC August 2013

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09.06.14 *SMC Report No. 963/14*	canagliflozin, 100mg and 300mg film-coated tablets (Invokana®) *Janssen-Cilag International NV* *In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control*.	Restricted use: canagliflozin (Invokana®) is accepted for restricted use within NHS Scotland in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: to use in the following situations: • dual therapy in combination with metformin • triple therapy in combination with metformin plus standard of care • add-on to insulin therapy in combination with insulin plus standard of care Treatment with canagliflozin reduces glycosylated haemoglobin (HbA1c) significantly more than placebo when used in combination with various anti-hyperglycaemic regimens (metformin, metformin and sulfonylurea, metformin and pioglitazone, insulin with/without additional anti-hyperglycaemic agents). In addition to metformin, canagliflozin was non-inferior to a sulfonylurea and a dipeptidyl peptidase-4 (DPP-4) inhibitor. In combination with metformin and sulfonylurea, canagliflozin was non-inferior to a DPP-4 inhibitor. Canagliflozin is also associated with reductions in body weight and systolic blood pressure. Canagliflozin is also licensed for use as monotherapy. The manufacturer's submission related only to the use of canagliflozin as add-on therapy with other glucose-lowering medicinal products. SMC cannot recommend the use of canagliflozin as monotherapy.	**Not included** on the LJF because clinicians do not support the formulary inclusion. The current LJF choice is dapagliflozin. FC July 2014
08.11.10 *SMC Report No. 658/10* NON SUBMISSION	canakinumab (Ilaris®) 150 mg/mL, powder for solution for injection intended *Novartis Pharmaceuticals* *Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg.*	NOT RECOMMENDED: canakinumab (Ilaris®) 150 mg/mL, powder for solution for injection intended is not recommended for use within NHSScotland. Indication under review: Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result SMC cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.06.13 *SMC Report No. 882/13* NON SUBMISSION	canakinumab (Ilaris®) 150 mg powder for solution for injection *Novartis Pharmaceuticals Ltd* *Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above.*	NOT RECOMMENDED**:** canakinumab (Ilaris®) is not recommended for use within NHS Scotland for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above including: • Muckle-Wells Syndrome (MWS) • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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10.06.13 *SMC Report No. 883/13* NON SUBMISSION	canakinumab (Ilaris®) 150 mg powder for solution for injection *Novartis Pharmaceuticals Ltd* *Symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.*	NOT RECOMMENDED: canakinumab (Ilaris®) is not recommended for use within NHS Scotland for symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.11.13 *SMC Report No. 926/13* NON SUBMISSION	canakinumab (Ilaris®) 150mg powder for solution for injection *Novartis Pharmaceuticals UK Limited* *Treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.*	NOT RECOMMENDED: canakinumab (Ilaris®) is not recommended for use within NHS Scotland for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.05.05 *SMC Report No. 161/05*	candesartan cilexetil 2, 4, 8, 16 and 32mg tablets (Amias®) *Takeda* *New indication: Treatment of patients with heart failure and left ventricular systolic dysfunction (left ventricular ejection fraction (LVEF) = 40%) as add-on therapy to ACE-inhibitors or when ACE-inhibitors are not tolerated.*	Accepted for use: candesartan (Amias®) is accepted for use within NHS Scotland for the treatment of patients with heart failure and left ventricular systolic dysfunction (left ventricular ejection fraction = 40%) as add-on therapy to ACE inhibitors or in patients who are unable to tolerate ACE inhibitors. Treatment with candesartan reduces mortality and hospitalisation due to heart failure. Candesartan may be used as a second-line agent in patients with chronic heart failure and LVEF = 40% following treatment with an ACE inhibitor and diuretic and with or without a beta-blocker.	Already included in the Formulary as first choice angiotensin-II receptor antagonist for treatment of hypertension and heart failure. FC September 2004
11.04.11 *SMC Report No: 703/11* NON SUBMISSION	cannabinoid oromucosal spray (Sativex ®) *Bayer plc.* *Treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS).*	NOT RECOMMENDED: cannabinoid oromucosal spray (Sativex ®) is not recommended for use within NHS Scotland. Indication under review: as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.03.03 *SMC Report No. 34/03*	capecitabine (Xeloda®) *Roche* *Advanced / metastatic breast cancer.*	Restricted use: capecitabine (Xeloda®) is accepted for restricted use within NHS Scotland. Capecitabine is recommended for use in Scotland by oncologists with appropriate expertise in treating locally advanced/metastatic breast cancer. It is an orally active treatment which has improved outcomes both as monotherapy in those previously treated with an anthracycline and a taxane, and in combination with docetaxel in those previously treated with an anthracycline.	Included in the Formulary.

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05.08.05 *SMC Report No. 193/05*	capecitabine 150 and 500mg tablets (Xeloda®) *Roche* *New indication: Adjuvant treatment of Dukes' C colon cancer.*	Accepted for use: capecitabine (Xeloda®) is accepted for use within NHS Scotland for the adjuvant treatment of patients following surgery for Stage III (Dukes' C stage) colon cancer. Oral capecitabine appears to be as least as effective as standard IV 5FU/FA chemotherapy with the convenience of oral administration. It should only be prescribed by oncologists. It is more expensive than IV chemotherapy regimens. However, its use may allow changes to service delivery that have individual patient or organisational benefits.	Added to the Additional List, for Specialist Use only. FC October 2005
10.09.07 *SMC Report No. 401/07*	capecitabine, 150mg and 500mg tablets (Xeloda®) *Roche* *First line treatment of patients with advanced gastric cancer in combination with a platinum based chemotherapy regimen.*	Accepted for use: capecitabine (Xeloda®) is accepted for use within NHS Scotland for first line treatment of patients with advanced gastric cancer in combination with a platinum-based chemotherapy regimen. Capecitabine was non-inferior to continuously infused intravenous 5-FU in terms of progression-free survival when each was used in combination with a platinum-based drug in patients with advanced gastric cancer. It also demonstrated non-inferiority in overall survival compared with continuously infused intravenous 5-FU in patients with advanced gastric cancer when each was used in a triple regimen containing a platinum-based drug and an anthracycline drug. Capecitabine is more expensive than 5-FU, however, the convenience of oral administration may allow changes to service delivery that have individual patient or organisational benefits.	Added to the Additional List, for Specialist Use only. FC January 2009
13.10.08 *SMC Report No. 507/08*	capecitabine 150mg and 500mg tablets (Xeloda®) *Roche Products Limited* *Treatment of metastatic colorectal cancer.*	Accepted for use: capecitabine 150mg and 500mg tablets (Xeloda®) is accepted for use within NHS Scotland for the treatment of metastatic colorectal cancer. The convenience of oral administration may allow changes to service delivery that have individual patient or organisational benefits, though these may be lessened when it is used in regimens whose other components require intravenous administration.	Added to the Additional List – for Specialist Use only. Approved under ADTC unlicensed medicines policy in January 2005. FC August 2009
08.08.11 *SMC Report No. 716/11*	capecitabine, 150mg, 500mg, tablets (Xeloda®) *Roche Products Limited* *Adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer in combination with oxaliplatin.*	Accepted for use: capecitabine (Xeloda®) is accepted for use within NHS Scotland. Indication under review: The adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer in combination with oxaliplatin. At 55 months, disease free survival was significantly increased for capecitabine plus oxaliplatin-treated patients compared with a recognised regimen containing a fluoropyramidine in the adjuvant treatment of patients with completely resected stage III (Dukes' C) colon cancer.	Added to the Additional List, for Specialist Use only. FC August 2011
07.02.11 *SMC Report No. 673/11*	capsaicin, 179mg, cutaneous patch (Qutenza®) *Astellas Pharma UK Limited* *Treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.*	Restricted use: capsaicin (Qutenza®) is accepted for restricted use within NHS Scotland. Indication under review: For the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. SMC restriction: use of this product is restricted to the treatment of adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first and second-line treatments. Treatment should be under the supervision of a specialist in pain management. Evidence was presented for patients with PHN only. Capsaicin patch significantly reduced pain scores compared to a low-concentration control patch in three clinical studies. The manufacturer did not submit data on the use of capsaicin patch in other neuropathies therefore SMC cannot recommend its use in these patient groups	Added to the Additional List, for Specialist Use only, dependent upon appropriate training in the administration of the patches. FC August 2011

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07.08.06 *SMC Report No. 309/06* NON SUBMISSION	carbetocin (Pabal®) 100micrograms/1mL solution for injection *Ferring Pharmaceuticals Ltd* *Prevention of uterine atony and excessive bleeding following delivery of the infant by Caesarean section under epidural or spinal anaesthesia.*	NOT RECOMMENDED: carbetocin (Pabal®) 100micrograms/1mL solution for injection, is not recommended for use within NHSScotland for the prevention of uterine atony and excessive bleeding following delivery of the infant by Caesarean section under epidural or spinal anaesthesia. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.08.05 *SMC Report No. 191/05* PRODUCT UPDATE (abbreviated submission)	carbomer 0.25% gel (Liquivisc®) *Allergan Ltd* *Symptomatic treatment of dry eye syndrome.*	Accepted for use: carbomer 0.25% (Liquivisc®) gel is accepted for use in NHS Scotland for the symptomatic treatment of dry eye syndrome where a carbomer product is the treatment of choice. It differs in only minor respects from other carbomer products and is less expensive.	Formulary entry to be amended to include generic carbomers instead of the branded products. FC August 2005
09.10.06 *SMC Report No. 299/06*	carglumic acid 200mg dispersible tablets (Carbaglu®) *Orphan Europe* *Treatment of hyperammonaemia due to N-acetylglutamate synthase deficiency.*	Restricted use: carglumic acid (Carbaglu®) is accepted for restricted use within NHS Scotland for the treatment of hyperammonaemia due to N-acetylglutamate synthase deficiency. Limited data from retrospective case analysis indicate that carglumic acid generally allowed patients to maintain normal ammonia levels, growth and psychomotor development. Carglumic acid is restricted to use by experts providing the supraregional specialist service for this disease.	Added to the Additional List, only if initiated by specialists working in the supraregional service for this disease. FC April 2008
07.10.13 *SMC Report No. 899/13*	carglumic acid 200mg dispersible tablets (Carbaglu®) *Orphan Europe (UK) Limited* *Hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.*	Accepted for use: carglumic acid (Carbaglu®) is accepted for use within NHS Scotland for hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia. The available clinical evidence for carglumic acid, although limited, suggests that plasma ammonia is reduced rapidly to non-toxic levels in life-threatening situations where rapid initiation of treatment is essential.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC November 2013
12.12.05 *SMC Report No. 215/05*	carmustine 7.7mg implant (Gliadel®) *Link Pharmaceuticals Ltd* *New indication: in newly diagnosed high-grade malignant glioma patients as an adjunct to surgery and radiation.*	Accepted for use: carmustine implant (Gliadel®) is accepted for use within NHS Scotland for the treatment of newly diagnosed high-grade malignant glioma patients as an adjunct to surgery and radiation. In the pivotal study, the use of carmustine implants was associated with a 29% relative decrease in the risk of death, which equates to an increase in median survival time of 2.3 months.	Added to the Additional List, for Specialist Use only. FC March 2006
09.01.04 *SMC Report No. 74/03*	caspofungin (Cancidas®) *Merck Sharpe & Dohme Ltd* *Invasive candidiasis in non-neutropenic adults.*	Restricted use: caspofungin (Cancidas®) provides an additional agent for the treatment of invasive candidiasis. Its use should be restricted to patients with fluconazole-resistant *Candida* infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at an increased risk of serious side effects with amphotericin (e.g. transplant patients, especially those receiving bone marrow transplants).	Added to the Additional List, for Specialist Use only in patients with fluconazole-resistant *Candida* infection as recommended by the SMC. FC March 2004

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07.02.05 *SMC Report No. 147/04*	caspofungin 50mg and 70mg powder for concentrate for solution for infusion (Cancidas®) *Merck Sharpe & Dohme* *New indication: empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropenic adult patients.*	Restricted use: caspofungin (Cancidas®) is accepted for restricted use within NHS Scotland for the empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropenic adult patients. It should be restricted to patients under the care of specialists experienced in the management of fungal disease. A comparative study found that caspofungin was as effective as a lipid formulation of amphotericin in terms of overall response. In addition it was better tolerated with fewer drug-related adverse events including less nephrotoxicity and infusion-related events. It is less expensive than another formulation of liposomal amphotericin, which has a licence for empirical use.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
07.03.03 *SMC Report No. 30/03*	caspofungin acetate (Cancidas®) *Merck Sharpe & Dohme Ltd* *Invasive aspergillosis.*	NOT RECOMMENDED: caspofungin acetate (Cancidas®) efficacy and safety data provided to support the possible benefits of caspofungin in the treatment of invasive aspergillosis were extremely limited, and in the form of one small, open-label, uncontrolled study. This evidence is not considered sufficiently robust to justify a recommendation for use at present. The applicant company has since confirmed that the results of a randomised clinical trial have been published in December 2002. The SMC will provide a further recommendation on this product once an additional submission has been made and assessed.	NOT RECOMMENDED
11.05.09 SMC Report No. 551/09 PRODUCT UPDATE (abbreviated submission)	caspofungin 50mg and 70mg powder for concentrate for solution for infusion (Cancidas®) *Merck Sharp & Dohme Ltd* Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropenic paediatric patients (12 months to 17 years).	Accepted for use: caspofungin acetate (Cancidas®) is accepted for use within NHS Scotland as empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropenic paediatric patients (12 months to 17 years). The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults. A comparative study in adults found that caspofungin was as effective as a lipid formulation of amphotericin in terms of overall response. In addition it was better tolerated with fewer drug-related adverse events including less nephrotoxicity and infusion-related events.	Added to the Additional List, Specialist Use only. FC May 2009
11.05.09 SMC Report No. 552/09 PRODUCT UPDATE (abbreviated submission)	caspofungin 50mg and 70mg powder for concentrate for solution for infusion (Cancidas®) *Merck Sharp & Dohme Ltd* *Ttreatment of invasive candidiasis in paediatric patients (12 months to 17 years).*	Restricted use: caspofungin acetate (Cancidas®) is accepted for restricted use within NHS Scotland for the treatment of invasive candidiasis in paediatric patients (12 months to 17 years). The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults. Caspofungin provides an additional agent for the treatment of invasive candidiasis. Its use should be restricted to patients with fluconazole-resistant Candida infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at an increased risk of serious side effects with amphotericin (eg. transplant patients, especially those receiving bone marrow transplants).	Added to the Additional List, Specialist Use only. FC May 2009
09.04.12 *SMC Report No. 788/12* NON SUBMISSION	catumaxomab (Removab®) 10 and 50 microgram concentrate for solution for infusion *Fresenius Biotech GmbH* *Intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible.*	NOT RECOMMENDED: catumaxomab (Removab®) is not recommended for use within NHS Scotland for intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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14.01.13 *SMC Report No. 830/12*	ceftaroline fosamil, 600mg, powder for concentrate for solution for infusion (Zinforo®) *AstraZeneca UK Ltd* *Treatment of complicated skin and soft tissue infections in adults.*	Restricted use: ceftaroline fosamil (Zinforo®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft tissue infections in adults. SMC restriction: use in patients with known or suspected meticillin resistant Staphylococcus aureus (MRSA) infection in the following settings: • For Gram-positive only infections where vancomycin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv or linezolid iv is normally used. • For polymicrobial Gram-positive and common Gram-negative pathogens*, where vancomycin iv in combination with gentamicin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv in combination with gentamicin iv, or linezolid iv in combination with gentamicin iv, or tigecycline iv is normally used. Ceftaroline should be used only on the advice of local microbiologists or specialists in infectious disease. In two randomised, controlled clinical studies, intravenous ceftaroline fosamil was non-inferior to intravenous vancomycin plus aztreonam in adult patients with complicated skin and skin structure infections. Ceftaroline is also licensed for the treatment of community acquired pneumonia. As the company submission related only to the treatment of skin and soft tissue infections, SMC cannot recommend the use of ceftaroline in community acquired pneumonia.	**Included** on the Additional List, Specialist Use only, for the indication in question. Ceftaroline has been classified as an alert antibiotic. FC March 2013
09.12.13 *SMC Report No. 932/13* NON SUBMISSION	cefuroxime sodium (Aprokam®) 50 mg powder for solution for injection Spectrum Thea Pharmaceuticals Limited Antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.	NOT RECOMMENDED: cefuroxime sodium (Aprokam®) is not recommended for use within NHS Scotland for antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.09.07 *SMC Report No. 410/07* NON SUBMISSION	celecoxib (Celebrex®) *Pharmacia Limited* *Ankylosing spondylitis.*	NOT RECOMMENDED: celecoxib (Celebrex®) is not recommended for use within NHS Scotland for ankylosing spondylitis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
11.10.10 *SMC Report No: 590/09* RESUBMISSION Patient Access Scheme	certolizumab pegol, 200 mg/mL solution for injection (prefilled syringe) (Cimzia®) UCB Pharma Ltd *Certolizumab pegol, in combination with methotrexate, is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drugs (DMARDs), including methotrexate, has been inadequate.* *Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. It has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.*	Accepted for use: certolizumab pegol (Cimzia®) is accepted for use within NHS Scotland. Indication under review: - in combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drugs, including methotrexate, has been inadequate. - monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. In patients who continued to receive methotrexate despite an incomplete response, the addition of certolizumab pegol for 24 weeks produced a rapid and sustained reduction in the signs and symptoms of rheumatoid arthritis, inhibited structural joint damage progression and improved physical function compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab pegol. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the LJF as first choice. FC January 2011
12.05.14 *SMC Report No: 960/14* Patient Access Scheme	certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®) *UCB Pharma UK* *Indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising:* *- Ankylosing spondylitis (AS)* *Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).* *- Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA)* *Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and /or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.*	Accepted for use: certolizumab pegol (Cimzia®) is accepted for use within NHS Scotland for the treatment of adult patients with severe active axial spondyloarthritis, comprising: - Ankylosing spondylitis (AS) Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). - Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA) Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and /or MRI, who have had an inadequate response to, or are intolerant to NSAIDs. In a randomised double-blind study, conducted in axial spondyloarthritis patients, including AS and nr-axSpA patients, there was a significantly higher proportion of Assessment of SpondyloArthritis International Society 20% responders at week 12 for certolizumab pegol- compared to placebo-treated patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the LJF as a first choice drug, for Specialist Use only, for the indication in question. FC July 2014

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
07.07.14 *SMC Report No. 973/14* Patient Access Scheme	certolizumab pegol, 200mg/mL, solution for injection in pre-filled syringe (Cimzia®) *UCB Pharma UK* *In combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.*	Restricted use: certolizumab pegol (Cimzia®): is accepted for restricted use within NHS Scotland in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. SMC restriction: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination. In a phase III, randomised, placebo-controlled study in patients with active psoriatic arthritis, significantly more patients who received certolizumab pegol achieved at least 20% response on the American College of Rheumatology criteria (ACR 20) at 12 weeks compared with those who received placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab pegol. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the LJF as a first choice drug, for Specialist Use only, for the indication in question. FC July 2014
10.10.05 *SMC Report No. 155/05* FOLLOWING INDEPENDENT REVIEW PANEL ASSESSMENT Superseded by MTA 242 January 2012	cetuximab 100mg in 50mL solution for infusion (Erbitux®) *Merck Pharmaceuticals Ltd* *In combination with irinotecan for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy.*	NOT RECOMMENDED: cetuximab (Erbitux®) is not recommended for use within NHS Scotland in combination with irinotecan for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy. MTA 242 Cetuximab monotherapy or combination chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.	NOT RECOMMENDED
10.07.06 *SMC Report No. 279/06*	cetuximab 2mg/mL intravenous infusion (Erbitux®) *MerckKGaA* *In combination with radiation therapy for the treatment of patients with locally advanced squamous cell cancer of the head and neck.*	Restricted use: cetuximab (Erbitux®) is accepted for restricted use within NHS Scotland in combination with radiation therapy for the treatment of patients with locally advanced squamous cell cancer of the head and neck. It is restricted to patients who are not appropriate for or unable to tolerate chemo-radiotherapy and who are of good performance status with no evidence of distant metastases. It is also restricted to use by specialists in the management of head and neck cancer.	Added to the Additional List, for Specialist Use only. FC September 2006
09.03.09 *SMC Report No. 547/09* NON SUBMISSION	cetuximab 5mg/mL solution for infusion (Erbitux®) *Merck Serono* *Treatment of patients with squamous cell cancer of the head and neck in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.*	NOT RECOMMENDED: cetuximab (Erbitux®) is not recommended for use within NHS Scotland for the treatment of patients with squamous cell cancer of the head and neck in combination with platinum-based chemotherapy for recurrent and/or metastatic disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
08.02.10 *SMC Report No. 543/09* RESUBMISSION Patient Access Scheme	cetuximab, 100mg/20mL and 500mg/100mL solution for intravenous infusion (Erbitux®) *Merck Serono Ltd* *Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten rat sarcoma (KRAS) wild-type metastatic colorectal cancer in combination with chemotherapy.*	Restricted use: cetuximab (Erbitux®) is accepted for restricted use within NHS Scotland for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten rat sarcoma (KRAS) wild-type metastatic colorectal cancer in combination with chemotherapy. Post hoc analyses from one phase III and one phase II study in patients with KRAS wild-type status who had not previously received chemotherapy for metastatic disease, showed an increase in overall response rate and a small, but statistically significant, increase in median progression free survival time, when cetuximab was added to standard first-line combination chemotherapy. Cetuximab is restricted to use in patients who have not previously received chemotherapy for their metastatic disease, with liver metastases only that are considered non-resectable but in whom potentially curative liver metastasis resection would be undertaken if the lesions became resectable after treatment with chemotherapy and cetuximab. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cetuximab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist use only. FC August 2011
12.08.13 *SMC Report No. 885/13*	chloroprocaine hydrochloride, 10mg/mL, solution for injection (Ampres®) *Mercury Pharmaceuticals Ltd* *Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes.*	NOT RECOMMENDED: chloroprocaine hydrochloride (Ampres®) is not recommended for use within NHS Scotland as spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes. In a small, single-centre, randomised, double-blind, controlled study spinal anaesthesia with chloroprocaine injection compared with a hyperbaric formulation of an amide-type local anaesthetic agent was associated with a faster resolution of sensory and motor block, resulting in a shorter time to meet eligibility criteria for discharge. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
09.10.06 *SMC Report No. 263/06* PRODUCT UPDATE (abbreviated submission)	choriogonadotropin alfa (Ovitrelle®) 250micrograms/0.5mL pre filled syringe *Serono Ltd* *Superovulation prior to assisted reproductive techniques such as in vitro fertilisation (IVF).*	Accepted for use: choriogonadotropin alfa 250micrograms/0.5mL pre-filled syringe (Ovitrelle®) is accepted for use in NHS Scotland for use in women undergoing superovulation prior to assisted reproduction techniques such as in vitro fertilisation, where the use of this preparation is appropriate. Unlike the vial formulation available previously it does not require reconstitution, and the cost per dose is the same. This replaces advice previously issued by the Scottish Medicines Consortium for Ovitrelle in May 2006 following a non-submission.	New formulation of a drug already included in the Formulary. FC October 2007
09.10.06 *SMC Report No. 264/06* PRODUCT UPDATE (abbreviated submission)	choriogonadotropin alfa (Ovitrelle®) 250micrograms/0.5mL pre filled syringe *Serono Ltd* *Treatment of anovulatory or oligo-ovulatory women.*	Accepted for use: choriogonadotropin alfa 250micrograms/0.5mL pre-filled syringe (Ovitrelle®) is accepted for use in NHS Scotland for the treatment of anovulatory or oligo-ovulatory women, where the use of this preparation is appropriate. Unlike the vial formulation available previously it does not require reconstitution, and the cost per dose is the same. This replaces advice previously issued by the Scottish Medicines Consortium for Ovitrelle in May 2006 following a non-submission.	New formulation of a drug already included in the Formulary. FC October 2007
11.07.05 *SMC Report No. 184/05*	ciclesonide 80, 160micrograms inhaler (Alvesco®) *Altana Pharma Limited* *Prophylactic treatment of persistent asthma in adults (18 years and older).*	Restricted use: ciclesonide (Alvesco®) is accepted for restricted use within NHS Scotland for the prophylactic treatment of persistent asthma in adults (18 years and older). Ciclesonide is restricted to asthma patients who require once a day administration and whose treatment is at step 2 or step 3 of the British Guideline on the Management of Asthma. Alternative inhaled steroids are available at lower costs.	To remain 'Not preferred' in Lothian as effective alternatives available. FC April 2006

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
12.06.06 *SMC Report No. 249/06*	ciclesonide, 40-160micrograms metered dose inhaler (Alvesco®) *Altana Pharma* *Treatment to control persistent asthma in adolescents (aged at least 12 years and <18 years).*	Restricted use: ciclesonide (Alvesco®) is accepted for restricted use within NHS Scotland for treatment to control persistent asthma in adolescents (aged at least 12 years and <18 years). It is restricted to asthma patients who require once-daily administration of an inhaled corticosteroid and whose treatment is at step 2 or step 3 of the British Guideline on the Management of Asthma. Alternative inhaled steroids are available at lower cost.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
12.11.07 *SMC Report No. 412/07* PRODUCT UPDATE (abbreviated submission)	ciclesonide 80micrograms, 160micrograms inhaler (Alvesco®) *Altana Pharma Ltd* *At high doses (up to 640micrograms daily for up to 12 weeks) to control persistent asthma in adolescents and adults (12 years and older).*	Accepted for use: ciclesonide inhaler (Alvesco®) is accepted for use within NHS Scotland at high doses (up to 640micrograms daily for up to 12 weeks) to control persistent asthma in adolescents and adults (12 years and older). The higher dose should be used in patients for whom ciclesonide is an appropriate choice of maintenance inhaled corticosteroid therapy. Alternative inhaled steroids are available at lower costs.	'Not preferred' as suitable alternatives exist. FC October 2007
07.11.05 *SMC Report No. 86/04* RESUBMISSION	cilostazol 100mg tablets (Pletal®) *Otsuka* *Improvement of the maximal and pain-free walking distances in patients with intermittent claudication, who do not have rest pain and who do not have evidence of peripheral tissue necrosis.*	NOT RECOMMENDED: cilostazol (Pletal®) is not recommended for use within NHS Scotland for improvement of the maximal and pain-free walking distances in patients with intermittent claudication, who do not have rest pain and who do not have evidence of peripheral tissue necrosis. Although in clinical trials, cilostazol improved pain-free and maximal-walking distances and had limited effects on quality of life assessments of physical function and pain, its efficacy and safety profile in Scottish patients, who are concomitantly treated with an antiplatelet drug, is unclear. The clinical effectiveness and cost-effectiveness were not demonstrated.	NOT RECOMMENDED
10.04.06 *SMC Report No. 169/05* RESUBMISSION	cinacalcet 30mg, 60mg and 90mg tablets (Mimpara®) *Amgen* *Treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.*	SMC - not recommended for use. NICE - recommends for use (NICE technology appraisal guidance 117. Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. January 2007. www.nice.org.uk/page.aspx?o=TA117) NHS QIS www.nhshealthquality.org/nhsqis advises that NICE technology appraisal 117 recommendations are as valid for Scotland as for England and Wales.	Added to the LJF as a prescribing note. FC May 2007
08.05.06 *SMC Report No. 271/06* NON SUBMISSION	cinacalcet 30, 60 and 90 mg film-coated tablets (Mimpara®) *Amgen Ltd* *Reduction of hypercalcaemia in patients with parathyroid carcinoma.*	NOT RECOMMENDED: cinacalcet (Mimpara®) is not recommended for use within NHSScotland for the reduction of hypercalcaemia in patients with parathyroid carcinoma. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.10.08 *SMC Report No. 513/08* NON SUBMISSION	cinacalcet 30mg, 60mg & 90mg (Mimpara®) *Amgen Ltd* *Treatment for the reduction of hypercalcaemia in patients with primary hyperparathyroidism (HPT).*	NOT RECOMMENDED: cinacalcet 30mg, 60mg & 90mg (Mimpara®) is not recommended for use within NHS Scotland for the reduction of hypercalcaemia in patients with primary hyperparathyroidism (HPT) for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED

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09.03.09 *SMC Report No. 537/09* PRODUCT UPDATE (abbreviated submission)	cladribine 2mg/mL solution for injection (LITAK®) *Lipomed GmbH* *Treatment of hairy cell leukaemia.*	Accepted for use: cladribine (Litak®) is accepted for use in NHS Scotland for the treatment of hairy cell leukaemia. In patients for whom cladribine is an appropriate agent for this indication, the 2mg/mL solution allows administration by subcutaneous bolus injection over five consecutive days rather than by continuous intravenous infusion of the existing 1mg/mL solution for seven consecutive days. This may confer advantages in terms of convenience to patients and service delivery at a lower cost per course.	New formulation of a product already included in the Additional List. FC March 2009
13.02.06 *SMC Report No. 217/05* PRODUCT UPDATE (abbreviated submission)	clarithromycin 125mg, 187.5mg, 250mg granules for oral suspension (ClaroSip®) *Grunenthal Ltd* *Treatment of acute and chronic infections caused by clarithromycin susceptible organisms.*	NOT RECOMMENDED: clarithromycin as ClaroSip® granules for oral suspension is not recommended for use within NHS Scotland for the treatment of acute and chronic infections caused by clarithromycin susceptible organisms. It uses sip technology, where the granules are contained within a drinking straw. ClaroSip® incurs a cost premium of up to 20% compared to alternative oral liquid clarithromycin, with no proven advantage in terms of compliance.	NOT RECOMMENDED
13.04.04 *SMC Report No. 92/04*	clindamycin 1% and benzoyl peroxide 5% gel (Duac® Once Daily) *Stiefel Laboratories* *Mild to moderate acne vulgaris.*	Restricted use: Duac® Once Daily is accepted for restricted use within NHS Scotland for the treatment of mild to moderate acne vulgaris. It should be considered after using benzoyl peroxide monotherapy and only when the addition of a topical antibiotic is deemed clinically necessary. Compared to other combination products, Duac® offers the advantage of once daily use at no additional cost.	Added to the Additional List. Duac® should be considered after benzoyl peroxide monotherapy and only when addition of topical antibiotic is deemed clinically necessary FC June 2004 Added to the LJF as a prescribing note for the treatment of mild to moderate acne vulgaris. FC November 2009
10.07.06 *SMC Report No. 280/06* PRODUCT UPDATE (abbreviated submission)	clobetasol propionate 0.05% cutaneous foam (Clarelux®) *3M Health Care Ltd* *Short-course treatment of steroid responsive dermatoses of the scalp such as psoriasis, which do not respond satisfactorily to less potent steroids.*	Accepted for use: clobetasol propionate 0.05% cutaneous foam (Clarelux®) is accepted for use within NHS Scotland for short-course treatment of steroid responsive dermatoses of the scalp such as psoriasis, which do not respond satisfactorily to less potent steroids. It offers an alternative to other scalp applications of clobetasol propionate at a similar cost (depending on the rate of application).	New formulation of a drug already included in the Formulary. FC October 2007
11.08.08 *SMC Report No. 434/07* RESUBMISSION	clobetasol propionate 0.05% shampoo (Etrivex®) *Galderma (UK) Limited* *Topical treatment of moderate scalp psoriasis in adults.*	Accepted for use: clobetasol propionate 0.05% shampoo (Etrivex®) is accepted for use within NHS Scotland for the topical treatment of moderate scalp psoriasis in adults. Comparison of clobetasol propionate 0.05% shampoo to another clobetasol formulation demonstrated non-inferiority and costs are similar.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC November 2009

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15.01.07 *SMC Report No. 327/06*	clofarabine, 1mg/mL concentrate for solution for infusion (Evoltra®) *Bioenvision Limited* *Treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients (= 21 years) who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response.*	Restricted use: clofarabine (Evoltra®) is accepted for restricted use within NHS Scotland for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients (= 21 years) who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response. It is restricted to patients in whom clofarabine is being used as a treatment to bridge to HSCT and restricted to use by specialists in paediatric haemato-oncology. It is not cost effective when used for palliation.	Added to the Additional List, for Specialist Use only. FC March 2009
08.03.04 *SMC Report No. 88/04*	clopidogrel (Plavix®) *Sanofi-Synthelabo & Bristol-Myers Squibb* *Prevention of atherothrombotic events in acute coronary syndrome (without ST-segment elevation) in combination with aspirin.*	Restricted use: clopidogrel (Plavix®) is accepted for restricted use within NHS Scotland for the treatment of acute coronary syndrome (without ST-segment elevation) in combination with aspirin. It should be initiated only during an inpatient stay and only in patients in whom a diagnosis of acute coronary syndrome is confirmed with ECG changes or raised cardiac enzymes/markers. The maximum benefit appears within 3 months of starting treatment and the available information suggests that there is loss of benefit on stopping treatment. Benefits are greatest in patients with a high Thrombosis In Myocardial Infarction (TIMI) risk score (5 - 7).	Included in the Adult Formulary. Prescribing guideline states the criteria by which a patient would qualify for this treatment; the appropriate dose; and the duration of treatment. FC November 2004 and FC August 2006
13.08.07 SMC Report No 390/07	clopidogrel 75mg tablets (Plavix®) *Sanofi-aventis UK and Bristol-Myers Squibb Pharmaceuticals Ltd.* *Patients suffering from acute coronary syndrome – ST segment elevation acute MI, in combination with aspirin in medically treated patients eligible for thrombolytic therapy.*	Restricted use: clopidogrel (Plavix®) is accepted for restricted use within NHS Scotland for patients with ST segment elevation acute myocardial infarction (MI), in combination with aspirin, in medically treated patients eligible for thrombolytic therapy. The addition of short-term treatment with clopidogrel to long-term low dose aspirin has improved the patency rate of the infarct related artery as well as clinical endpoints. Treatment with clopidogrel in these patients is restricted to continuation for 4 weeks.	Already included in the formulary. Added to the Formulary as a Prescribing Note - to be used for up to 1 month post ST-elevation myocardial infarction (STEMI). FC August 2006
07.03.11 *SMC Report No. 80/03* 2ND RESUBMISSION	clostridium botulinum type A neurotoxin complex (Botox®) *Allergan* *Focal spasticity of the wrist and hand associated with stroke in adults.*	Accepted for use: clostridium botulinum toxin type A (Botox®) is accepted for use within NHS Scotland. Indication under review: focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults. In a placebo-controlled study, botulinum toxin type A was significantly superior to placebo in terms of the disability assessment scale and efficacy was maintained across repeated injections in an open-label extension study with a duration of one year.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012
14.01.13 *SMC Report No. 353/07* RESUBMISSION	clostridium botulinum type A toxin-haemagglutinin complex 300 units and 500 units (Dysport®) *Ipsen Limited* *Treatment of focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy.*	Restricted use: clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) is accepted for restricted use within NHS Scotland for the treatment of focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy. SMC restriction: for focal spasticity of the upper limbs associated with stroke. Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) produces a localised reduction in muscle tone in patients with post-stroke upper limb spasticity and can improve patient disability at 16 weeks. It continues to be effective after repeated administrations with no new adverse events apparent.	**Not included** on the LJF, pending protocol. FC April 2013

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09.06.08 *SMC Report No. 464/08*	clostridium botulinum neurotoxin type A, 100 unit powder for solution for injection (Xeomin®) *Merz Pharma UK Ltd* *Symptomatic management of blepharospasm and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults.*	Accepted for use: clostridium botulinum neurotoxin type A (Xeomin®) is accepted for use within NHS Scotland for the symptomatic management of blepharospasm and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults. For both indications, a similar improvement in symptoms has been shown compared to another clostridium botulinum neurotoxin type A.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC November 2009
12.05.14 *SMC Report No. 933/13* NON SUBMISSION	cobicistat (Tybost®) 150 mg film coated tablet *Gilead Sciences* *Pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults.*	NOT RECOMMENDED: cobicistat (Tybost®) is not recommended for use within NHS Scotland as a Pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.10.06 *SMC Report No. 316/06*	co-careldopa intestinal gel, 20mg/5mg levodopa/carbidopa per mL for continuous intestinal infusion (Duodopa®) *Solvay Healthcare Ltd* *Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.*	NOT RECOMMENDED: co-careldopa intestinal gel (Duodopa®) is not recommended for use within NHS Scotland for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. In the pivotal study an increase in "on" time was achieved compared with individually optimised conventional combinations of Parkinson's disease medication. However, the economic case has not been demonstrated.	NOT RECOMMENDED
10.09.12 *SMC Report No. 801/12*	colecalciferol 800 international units (equivalent to 20 micrograms vitamin D_3) capsules (Fultium-D_3®) *Internis Pharmaceuticals Limited* *In adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.*	Accepted for use: colecalciferol (Fultium-D3®) is accepted for use within NHS Scotland in adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. The therapeutic use and safety profile of colecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. There are no comparative data for Fultium-D3® as it is the first licensed oral vitamin D monotherapy formulation.	**Included** on the LJF for the indication in question. FC October 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.02.13 *SMC Report No. 840/13* PRODUCT UPDATE (abbreviated submission)	colecalciferol 800 international units (equivalent to 20 micrograms vitamin D_3) tablets (Desunin 800 IU®) *Meda* *Prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered.*	Accepted for use: colecalciferol tablets (Desunin 800 IU®) is accepted for use within NHS Scotland for the prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered. The therapeutic use and safety profile of colecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. There are no comparative data for colecalciferol (Desunin®). It is the same cost as another vitamin D preparation.	**Included** on the LJF for the indication in question. FC January 2013 **Included** on the LJF Child as a joint first choice drug, for the indication in question. FC May 2014
11.02.08 *SMC Report No. 451/08* NON SUBMISSION	colesevelam hydrochloride (Cholestagel®) *Genzyme Therapeutics Ltd* *Treatment of:* *- primary hypercholesterolaemia, co-administered with an HMG-CoA reductase inhibitor (statin), as adjunctive therapy to diet to provide an additive reduction in LDL-cholesterol levels in patients not adequately controlled with a statin alone* *- as monotherapy as adjunctive therapy to diet for reduction of elevated total and LDL- cholesterol in patients with isolated primary hypercholesterolaemia, in whom a statin is considered inappropriate or is not well tolerated.*	NOT RECOMMENDED: colesevelam hydrochloride (Cholestagel®), is not recommended for use within NHS Scotland for the treatment of: - primary hypercholesterolaemia, co-administered with an HMG-CoA reductase inhibitor (statin), as adjunctive therapy to diet to provide an additive reduction in LDL-cholesterol levels in patients not adequately controlled with a statin alone. - as monotherapy as adjunctive therapy to diet for reduction of elevated total and LDL-cholesterol in patients with isolated primary hypercholesterolaemia, in whom a statin is considered inappropriate or is not well tolerated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
07.02.11 *SMC Report No. 690/11* NON SUBMISSION	colesevelam 625mg film-coated tablets (Cholestagel®) *Genzyme Therapeutics* *In combination with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia.*	NOT RECOMMENDED: colesevelam (Cholestagel®) is not recommended for use within NHS Scotland. Indication under review: in combination with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.02.14 *SMC Report No. 939/14*	colestilan 1g film-coated tablet, 2g and 3g granules sachet (BindRen®) *Mitsubishi Pharma Europe* *Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.*	NOT RECOMMENDED: colestilan (BindRen®) is not recommended for use within NHS Scotland treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis. Colestilan, compared to placebo, reduces serum phosphate in dialysis patients with CKD and hyperphosphataemia. Comparative data with another non-calcium-based, non-absorbed phosphate binder do not provide robust evidence of equivalence. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED

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27.03.13 *NICE Techonolgy Appriasial No 276* Patient Access Scheme	colistimethate sodium 1,662,500 IU dry powder for inhalation (Colobreathe®) *Forest Laboratories UK Limited* *Colistimethate sodium DPI is an option for treating chronic pulmonary infection caused by P. aeruginosa in people with cystic fibrosis.*	NICE MTA 276 guidance recommends Colistimethate sodium DPI as an option for treating chronic pulmonary infection caused by P. aeruginosa in people with cystic fibrosis only if: •they would clinically benefit from continued colistimethate sodium but do not tolerate it in its nebulised form and thus tobramycin therapy would otherwise be considered and •the manufacturer provides colistimethate sodium DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS.	**Included** on the Additional List as a second-line threatment, for the indication in question (in adult patients), with Specialist Initiation. FC October 2013
14.05.12 *SMC Report No. 715/11* RESUBMISSION	collagenase clostridium histolyticum 0.9mg powder and solvent for solution for injection (Xiapex®) *Pfizer Ltd* *Treatment of Dupuytren's contracture in adult patients with a palpable cord.*	Restricted use: collagenase clostridium histolyticum (Xiapex®) is accepted for restricted use within NHS Scotland for the treatment of Dupuytren's contracture in adult patients with a palpable cord. SMC restriction: restricted to use as an alternative to limited fasciectomy in adult patients with Dupuytren's contracture of moderate severity (as defined by the British Society for Surgery of the Hand (BSSH), with a palpable cord and up to two affected joints per hand, who are suitable for limited fasciectomy, but for whom percutaneous needle fasciotomy is not considered a suitable treatment option. Collagenase clostridium histolyticum compared to placebo significantly reduces primary joint contracture in adults with Dupuytren's contracture and palpable cord. The cost-effectiveness of collagenase clostridium histolyticum relative to percutaneous needle fasciotomy was not demonstrated.	**Included** on the Additional List, for Specialist Use only. FC August 2012
10.10.11 SMC Report No. 745/11 NON SUBMISSION	conestat alfa (Ruconest ®) 2100 U powder for solution for injection *Swedish Orphan Biovitrium Ltd* *Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.*	NOT RECOMMENDED: conestat alfa (Ruconest ®) is not recommended for use within NHS Scotland treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.11.07 *SMC Report No. 413/07* PRODUCT UPDATE (abbreviated submission)	conjugated estrogen 0.3mg tablet (Premarin®) *Wyeth Pharmaceuticals* *As hormone replacement therapy for estrogen deficiency symptoms in postmenopausal women.*	Accepted for use: conjugated estrogen 0.3mg tablet (Premarin®) is accepted for use within NHS Scotland as hormone replacement therapy for estrogen deficiency symptoms in postmenopausal women. It should be used for patients in whom a conjugated estrogen is an appropriate choice of hormone replacement therapy and in whom the lower dose preparation provides adequate control of symptoms.	New formulation of a drug already included in the Formulary. FC October 2007
08.11.04 *SMC Report No. 130/04*	conjugated oestrogen, medroxyprogesterone (Premique® Low Dose) *Wyeth* *Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women with an intact uterus.*	Accepted for use: conjugated oestrogen 0.3mg, medroxyprogesterone 1.5mg (Premique® Low Dose) is accepted for use within NHS Scotland as hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women with an intact uterus. It is effective in controlling vasomotor symptoms and is associated with lower rates of breast pain and endometrial bleeding compared to other products with higher oestrogen content. It is more expensive than several other HRT therapies, but less expensive than the current market leader in Scotland.	Added to the Additional List. May be useful addition for those women who wish to reduce dose of HRT prior to stopping. FC January 2005

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13.07.10 SMC Report No. 633/10 NON SUBMISSION	corifollitropin alfa (Elonva®) 100 and 150mcg solution for injection *MSD* *Ttreatment of Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology program.*	NOT RECOMMENDED: corifollitropin alfa (Elonva®) is not recommended for use within NHSScotland for the treatment of Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.12.04 *SMC Report No. 141/04* PRODUCT UPDATE (abbreviated submission)	creon micro (Creon®) *Solvay Healthcare* *New formulation for infants: Treatment of pancreatic exocrine insufficiency.*	Restricted use: creon micro granule formulation (Creon®) is accepted for restricted use in NHS Scotland for the treatment of pancreatic exocrine insufficiency. It provides a formulation suitable for use in young infants and is expected to be used for young cystic fibrosis sufferers who are unable to swallow capsules. The associated resource implications are expected to be small.	New formulation of a drug already included in the Formulary. FC October 2007
07.10.13 *SMC Report No. 865/13* RESUBMISSION PATIENT ACCESS SCHEME	crizotinib, 200mg and 250mg, hard capsule (Xalkori®) *Pfizer Ltd.* *Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).*	Accepted for use: crizotinib (Xalkori®) is accepted for use within NHS Scotland for the treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). In a phase III clinical study in patients with previously treated anaplastic lymphoma kinase (ALK)-positive advanced NSCLC, crizotinib significantly increased progression-free survival compared with standard chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC November 2013
09.05.05 *SMC Report No. 164/05*	cytarabine 50mg liposomal suspension for injection (DepoCyte®) *Napp Pharmaceuticals* *Intrathecal treatment of lymphomatous meningitis.*	NOT RECOMMENDED: cytarabine liposomal suspension for injection (DepoCyte®) is not recommended for use within NHS Scotland for the intrathecal treatment of lymphomatous meningitis. Intrathecally administered cytarabine liposomal suspension cleared malignant cells from the cerebrospinal fluid, however effects on symptom improvement were not well defined and the cost-effectiveness compared to cytarabine solution has not been demonstrated.	NOT RECOMMENDED
09.06.08 *SMC Report No. 466/08*	dabigatran etexilate, 75mg and 110mg hard capsules (Pradaxa®) *Boehringer Ingelheim Ltd* *Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.*	Accepted for use: dabigatran etexilate (Pradaxa®) is accepted for use within NHS Scotland for the primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. In two large phase lll studies, in patients undergoing either total knee or total hip replacement surgery, dabigatran was non-inferior to low molecular weight heparin in the incidence of VTE and all cause mortality with patients having a similar incidence of major bleeding events. The two drugs have similar costs per dose but dabigatran has lower administration costs and is an oral therapy. This may facilitate longer duration of thromboprophylaxis, however the risks and benefits of this longer treatment duration need to be considered on a case-by-case basis.	'Not preferred' as suitable alternatives exist. FC December 2008

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12.09.11 *SMC Report No. 672/11*	dabigatran etexilate 110mg and 150mg hard capsules (Pradaxa®) *Boehringer Ingelheim Ltd* *For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more of the following risk factors:* *- previous stroke, transient ischaemic attack, or systemic embolism* *- left ventricular ejection fraction <40%* *- symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2* *- age ≥ 75 years* *- age ≥ 65 years associated with one of the following: diabetes mellitus, coronary artery disease or hypertension.*	Accepted for use: dabigatran etexilate (Pradaxa®) is accepted for use within NHS Scotland for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more of the following risk factors: • previous stroke, transient ischaemic attack, or systemic embolism • left ventricular ejection fraction <40% • symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2 • age ≥75 years • age ≥65 years associated with one of the following: diabetes mellitus, coronary artery disease or hypertension Dabigatran etexilate was at least as effective as standard oral anticoagulation at preventing stroke or systemic embolism in one large, open-label study in patients with atrial fibrillation and at least one risk factor for stroke. This was not associated with an increased risk of major bleeding. The economics case made supports the use of the proposed sequenced dosing regimen (whereby the dose is reduced from 150mg twice daily to 110mg twice daily in patients aged ≥ 80 years). . This applies whether the alternative treatment is warfarin, aspirin or 'no treatment' (i.e. neither warfarin nor aspirin).	'Not preferred' as suitable alternatives exist. FC December 2011
07.03.11 *SMC Report No. 683/11*	dalteparin sodium, 5,000IU/0.2mL, 7,500IU/0.3mL, 10,000IU/0.4mL, 12,500IU/0.5mL, 15,000IU/0.6mL, 18,000IU/0.72mL solution for injection. (Fragmin®) *Pfizer Ltd* *Extended treatment of symptomatic venous thromboembolism (VTE) and prevention of its recurrence in patients with solid tumours.*	Restricted use: dalteparin (Fragmin®) is accepted for restricted use within NHS Scotland. Indication under review: extended treatment of symptomatic venous thromboembolism (VTE) and prevention of its recurrence in patients with solid tumours. SMC restriction: initiation by healthcare professionals experienced in the treatment of VTE. In patients with cancer and VTE, dalteparin significantly reduced the rates of VTE recurrence over a six month period, compared to oral anticoagulation. Bleeding and mortality rates for patients receiving dalteparin were similar to those reported in patients receiving oral anticoagulant. The economic case was demonstrated for dalteparin compared to other low molecular weight heparins.	Added to the Formulary. FC December 2011

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14.01.13 *SMC Report No. 799/12*	dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®) *Bristol-Myers Squibb / AstraZeneca* *For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as:* *Add-on combination therapy* *In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.*	Restricted use: dapagliflozin (Forxiga®) is accepted for restricted use within NHS Scotland for use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: Add-on combination therapy In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: Dapagliflozin is restricted to use as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate. In three phase III randomised, controlled studies, dapagliflozin when added to metformin was non-inferior to a sulphonylurea in combination with metformin, and superior to placebo in terms of glycaemic control, as measured by change in HbA1c. This was accompanied by reductions in body weight and the risk of hypoglycaemia with dapagliflozin treatment was similar to placebo and lower, when compared with sulphonylurea. In a phase III randomised, controlled study, dapagliflozin treatment, when added to an insulin-containing regimen, was associated with; greater reductions in HbA1c, in body weight; and similar rates of hypoglycaemia when compared with placebo. The submitting companies did not present a sufficiently robust economic analysis to gain acceptance by SMC for use in addition to insulin in patients who have inadequate glycaemic control. Dapagliflozin is also licensed for use as monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. The manufacturers' submission related only to the use of dapagliflozin when used as dual therapy in combination with either metformin or insulin. SMC cannot recommend the use of dapagliflozin as monotherapy.	**Included** on the LJF as a prescribing note in combination with metformin for the indication in question as per SMC restriction. FC March 2013
10.03.14 *SMC Report No. 799/12* RESUBMISSION	dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®) *Bristol-Myers Squibb / AstraZeneca* For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control	Restricted use: dapagliflozin (Forxiga®) is accepted for restricted use within NHS Scotland. Indication under review: For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: In combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control. In a phase III randomised, controlled study, dapagliflozin treatment, when added to an insulin-containing regimen, was associated with: greater reductions in glycosylated haemoglobin (HbA1c), in body weight, and similar rates of hypoglycaemia when compared with placebo. Dapagliflozin is also licensed for use as monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. The companies' submission related only to the use of dapagliflozin when used in combination with insulin. SMC cannot recommend the use of dapagliflozin as monotherapy. SMC has previously accepted dapagliflozin for restricted use in combination with metformin.	**Included** on the LJF as a prescribing note in combination with insulin, for Specialist Initiation, for the indication in question. FC April 2014

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07.07.14 *SMC Report No. 799/12* 2nd RESUBMISSION	dapagliflozin 5mg and 10mg film-coated tablet (Forxiga®) *AstraZeneca* *In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.*	Restricted use: dapagliflozin (Forxiga®) is accepted for restricted use within NHS Scotland in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: in triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor. SMC has previously accepted dapagliflozin for use: ● as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate. ● in combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control. Dapagliflozin is also licensed for use as monotherapy but the company's resubmission did not relate to its use in this setting. SMC cannot recommend the use of dapagliflozin as monotherapy.	Formulary classification not yet decided – waiting for information from clinician.
07.07.14 *SMC Report No. 987/14* NON SUBMISSION	dapoxetine hydrochloride 30mg and 60 mg film-coated tablets (Priligy®) *A Menarini Farmaceutica Internazionale SRL* *Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.*	NOT RECOMMENDED: dapoxetine hydrochloride (Priligy®) is not recommended for use within NHS Scotland for the treatment of premature ejaculation (PE) in adult men aged 18 to 64 years. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.04.06 *SMC Report No. 248/06*	daptomycin 350mg powder for concentrate for solution for infusion (Cubicin®) *Chiron Corporation Limited* *Treatment of complicated skin and soft tissue infections in adults.*	Restricted use: daptomycin (Cubicin®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft tissue infections in adults. Daptomycin should be restricted to use in patients with known or suspected *methicillin-resistant Staphylococcus aureus* (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. Daptomycin has a higher acquisition cost than some alternative treatments; it does not, however, require therapeutic drug monitoring.	Added to the Additional List, for Specialist Use only. Use must be sanctioned by a consultant microbiologist or consultant in infectious diseases physician and the consultant in charge of the patient. FC December 2007
15.01.07 *SMC Report No. 338/06* PRODUCT UPDATE (abbreviated submission)	daptomycin 500 mg powder for intravenous infusion (Cubicin®) *Novartis Pharmaceuticals UK Ltd* *Treatment of complicated skin and soft-tissue infections in adults.*	Restricted use: daptomycin 500mg powder for intravenous infusion (Cubicin®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft-tissue infections in adults. Daptomycin should be restricted to use in patients with known or suspected *methicillin-resistant Staphylococcus aureus* (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. The new strength allows patients weighing over 87.5kg to be treated with a single 500mg vial at a reduced cost compared to two vials of the 350mg strength. Daptomycin has a higher acquisition cost than some alternative treatments; it does not, however, require therapeutic drug monitoring.	Added to the Additional List, for Specialist Use only. Use must be sanctioned by a consultant microbiologist or consultant in infectious diseases physician and the consultant in charge of the patient. FC December 2007

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10.03.08 *SMC Report No. 449/08*	daptomycin 350mg and 500 mg vials of powder for solution for infusion (Cubicin®) *Novartis Pharmaceuticals UK Limited* *Treatment of Staphylococcus aureus bacteraemia (SAB) when associated with right sided infective endocarditis (RIE) or with complicated skin and soft tissue infections (cSSTI) in adults.*	Restricted use: daptomycin, (Cubicin®) is accepted for restricted use within NHS Scotland for the treatment of Staphylococcus aureus bacteraemia (SAB) when associated with right-sided infective endocarditis (RIE) or with complicated skin and soft-tissue infections in adults. Daptomycin should be restricted to use in patients with known or suspected methicillin-resistant S. aureus (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. Daptomycin has been shown to be as effective as standard therapy in patients with S. aureus bacteraemia with or without endocarditis, though data on the subgroup of patients with RIE due to MRSA are very limited. Daptomycin has a higher acquisition cost than some alternative treatment; it does not, however, require therapeutic drug monitoring.	Added to the Additional List, for Specialist Use only. FC July 2009
08.05.06 *SMC Report No. 273/06* NON SUBMISSION	darbepoetin alfa (Aranesp®) *Amgen Ltd* *Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.*	NOT RECOMMENDED: darbepoetin alfa (Aranesp®) is not recommended for use within NHSScotland for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this formulation. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.05.06 *SMC Report No. 265/06* NON SUBMISSION	darbepoetin alfa (Aranesp®) SureClick *Amgen Ltd* *Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.*	NOT RECOMMENDED: darbepoetin alfa (Aranesp®) SureClick is not recommended for use within NHS Scotland for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this formulation. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
11.06.07 *SMC Report No. 377/07*	darifenacin 7.5mg, 15mg prolonged-release tablets (Emselex®) *Ardana Bioscience* *Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.*	Restricted use: darifenacin (Emselex®) is accepted for restricted use within NHS Scotland for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Darifenacin is effective in reducing symptoms associated with overactive bladder, including frequency, urgency and incontinence and the treatment effect is similar to another antimuscarinic. Darifenacin is associated with adverse effects typical of antimuscarinic agents used in this condition. It is restricted to second line use as there are cheaper antimuscarinics available that would normally be used as first-line agents.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC June 2008
11.06.07 *SMC Report No. 378/07*	darunavir 300mg tablets (Prezista®) *Tibotec (a division of Janssen-Cilag Ltd)* *Co-administered with ritonavir and in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated adult patients who have failed on more than one regimen containing a protease inhibitor (PI).*	Accepted for use: darunavir (Prezista®) is accepted for use within NHS Scotland, co-administered with ritonavir and in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated adult patients who have failed on more than one regimen containing a protease inhibitor (PI). At 24 and 48 weeks, darunavir, in combination with low dose ritonavir, showed a significant improvement in the reduction of viral load compared with other protease inhibitor plus ritonavir regimens.	Added to the Additional List. FC December 2007

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07.09.09 *SMC Report No. 566/09*	darunavir, 400mg tablets (Prezista®) *Tibotec, a division of Janssen-Cilag Ltd* *Co-administered with low dose ritonavir, is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV 1) infection in antiretroviral therapy (ART) naïve adults*	Accepted for use: darunavir (Prezista®) co-administered with low dose ritonavir and in combination with other antiretroviral medicinal products is accepted within NHS Scotland for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral therapy (ART) naïve adults. After 48 weeks the combination of darunavir and ritonavir was non-inferior to a standard boosted protease inhibitor regimen in ART naïve adults. The combined regimen was associated with lower incidences of diarrhoea and lipid adverse effects.	Added to the Additional List, for Specialist Use only. FC August 2010
08.02.10 *SMC Report No. 604/10* PRODUCT UPDATE (abbreviated submission)	darunavir 75mg, 150mg, 300mg, 600mg film-coated tablets (Prezista®) *Tibotec, a subsiduary of Janssen-Cilag* *Treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor (PI).*	Accepted for use: darunavir (Prezista®) is accepted for use within NHS Scotland, co administered with low dose ritonavir in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor (PI). Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. The Scottish Medicines Consortium has previously accepted this product for use in this indication in adults.	Added to the Additional List. FC March 2010
08.08.11 *SMC Report No. 707/11*	darunavir 400mg tablets (Prezista®) *Janssen* *Treatment of HIV-1 infection in antiretroviral therapy experienced adults*	Accepted for use: darunavir (Prezista®) 400mg is accepted for use within NHS Scotland. Indication under review: darunavir 800mg once daily co-administered with low dose ritonavir (100mg once daily) for the treatment of HIV-1 infection in antiretroviral therapy experienced adults with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm3. Darunavir 800mg/ritonavir 100mg once daily was demonstrated to be non inferior to darunavir 600mg/ritonavir 100mg twice daily, when administered with an optimised background regimen that consisted of at least two nucleoside reverse transcriptase inhibitors in treatment experienced HIV infected patients.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012
08.04.13 *SMC Report No. 861/13* PRODUCT UPDATE (abbreviated submission)	darunavir oral suspension 100mg/mL (Prezista®) *Janssen-Cilag Ltd* *Co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight.*	Restricted use: darunavir oral suspension (Prezista®) is accepted for restricted use within NHS Scotland co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight. SMC restriction: to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV. Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor.	**Included** on the LJF for the indication in question. FC April 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
10.03.14 *SMC Report No. 948/14* PRODUCT UPDATE (abbreviated submission)	darunavir 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) *Janssen-Cilag Ltd* *darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients 12 to 17 years of age and at least 40kg body weight who are: antiretroviral therapy (ART) naïve; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm^3.*	Restricted use: darunavir (Prezista®) is accepted for restricted use within NHS Scotland co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients 12 to 17 years of age and at least 40kg body weight who are: antiretroviral therapy (ART) naïve; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm3. SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV. The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor. Darunavir is listed in the British National Formulary for Children in combination with other antiretroviral drugs, for HIV infection resistant to other protease inhibitors in children previously treated with antiretrovirals.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC February 2014
07.05.07 *SMC Report No. 370/07* *Superseded by MTA 241 January 2012*	dasatinib, 20mg, 50mg, 70mg tablets (Sprycel®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *Treatment of adults with chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate.*	Restricted use: dasatinib, 20mg, 50mg, 70mg tablets (Sprycel®) is accepted for restricted use within NHS Scotland for the treatment of adults with chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate. It should be restricted to use in patients who are in the chronic phase of the disease. The manufacturer's justification of the treatment's cost in relation to its health benefits for the accelerated or blast phases was not sufficient to gain acceptance by SMC. MTA 241 Dasatinib is not recommended for the treatment of chronic, accelerated or blast-crisis phase CML in adults with imatinib intolerance or whose CML is resistant to treatment with standard-dose imatinib.	Added to the Additional List, Specialist Use only, for the treatment of CML in patients intolerant to, or not responding to, imatinib. FC March 2008 MTA 241 supersedes SMC advice and therefore supersedes FC decision. NOT RECOMMENDED
07.05.07 *SMC Report No. 371/07*	dasatinib, 20mg, 50mg, 70mg tablets (Sprycel®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *Treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia with resistance or intolerance to prior therapy.*	NOT RECOMMENDED: dasatinib 20mg, 50mg, 70mg (Sprycel®) is not recommended for use within NHS Scotland for the treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia with resistance or intolerance to prior therapy. It has been associated with haematological and cytogenetic responses in patients resistant or intolerant to existing treatment. However, the economic case was not sufficiently robust and the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
14.01.13 *SMC Report No. 846/12* NON SUBMISSION	decitabine (Dacogen®) 50 mg powder for concentrate for solution for infusion *Janssen-Cilag Ltd* *Treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.*	NOT RECOMMENDED: decitabine (Dacogen®) is not recommended for use within NHS Scotland for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
12.02.07 *SMC Report No. 347/07*	deferasirox, 125, 250, 500mg dispersible tablets (Exjade®) *Novartis Pharmaceuticals UK Limited* *Treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions.*	Restricted use: deferasirox (Exjade®) is accepted for restricted use within NHS Scotland for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions. It is not recommended for patients with myelodysplastic syndromes. Patients with myelodysplastic syndromes, the commonest cause of transfusion-dependent anaemia, were poorly represented in the clinical trial population and the economic case was not demonstrated in this group.	Added to the LJF as a prescribing note, for Specialist Use only. FC July 2007
08.04.13 *SMC Report No. 866/13* NON SUBMISSION	deferasirox (Exjade®) 125mg, 250mg and 500mg dispersible tablets *Novartis Pharmaceuticals UK Ltd* *Treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.*	NOT RECOMMENDED: deferasirox (Exjade®) is not recommended for use within NHS Scotland for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.06.14 *SMC Report No. 967/14* Patient Access Scheme	defibrotide, 80mg/mL, concentrate for solution for infusion (Defitelio®) *Gentium GmbH* *Treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy.*	Accepted for use: defibrotide (Defitelio®) is accepted for use within NHS Scotland for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy. In a phase III open-label study, defibrotide was associated with improved complete response rate and survival in patients with severe VOD, compared with a historical control group. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of defibrotide. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Not included** on the LJF, pending protocol. FC July 2014
17.01.11 *SMC Report No. 560/09* RESUBMISSION Patient Access Scheme	degarelix 120mg, 80mg powder and solvent for solution for injection (Firmagon®) *Ferring Pharmaceuticals Ltd* *For the treatment of adult male patients with advanced hormone-dependent prostate cancer.*	Accepted for use: degarelix (Firmagon®) is accepted for use within NHS Scotland. Degarelix is a gonadotropin-releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer. In one study that included patients with all stages of prostate cancer, degarelix was shown to be non-inferior to a luteinising hormone releasing hormone (LHRH) agonist in suppressing testosterone levels over a one year treatment period without an initial testosterone flare. This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of degarelix. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	**Included** on the Additional List for Specialist Use only and a prescribing note, for use in patients who are at risk of spinal cord compression. FC August 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.12.10 *SMC Report No. 651/10*	denosumab, 60mg solution for injection in a pre-filled syringe (Prolia®) *Amgen* *Treatment of osteoporosis in postmenopausal women at increased risk of fractures.*	Restricted use: denosumab (Prolia®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of osteoporosis in postmenopausal women at increased risk of fractures. Denosumab significantly reduces the risk of vertebral, non vertebral and hip fractures. SMC restriction: use only in patients with a bone mineral density (BMD) T-score < -2.5 and ≥ -4.0 for whom oral bisphosphonates are unsuitable due to contraindication, intolerance or inability to comply with the special administration instructions. Treatment with denosumab for three years significantly reduced the incidence of new vertebral, non-vertebral and hip fractures compared with placebo in postmenopausal women at increased risk of fractures.	Added to the Additional List, Specialist Use only FC April 2011
13.12.10 *SMC Report No. 670/10* NON SUBMISSION	denosumab 60mg solution for injection in pre-filled syringe (Prolia®) *Amgen Ltd* *Bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.*	NOT RECOMMENDED: denosumab (Prolia®) is not recommended for use within NHS Scotland. Indication under review: bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
October 2012 *NICE MTA 265* *Supersedes SMC Report No. 752/11*	denosumab 120 mg solution for injection (Xgeva®) *Amgen* *Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours.*	Denosumab is recommended as an option for preventing skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from breast cancer and from solid tumours other than prostate if: • bisphosphonates would otherwise be prescribed and • the manufacturer provides denosumab with the discount agreed in the patient access scheme.	**Included** on the LJF, Specialist Use only, for the indication in question. Application was for breast cancer patients only. FC April 2013
07.05.07 *SMC Report No. 358/07* PRODUCT UPDATE (abbreviated submission)	desmopressin 60, 120 and 240micrograms oral lyophilisate (DDAVP Melt®) *Ferring Pharmaceuticals Ltd* *Treatment of vasopressin-sensitive cranial diabetes insipidus and in the treatment of post-hypophysectomy polyuria/polydipsia.*	Accepted for use: desmopressin oral lyophilisate (DDAVP Melt®) is accepted for use in NHS Scotland for the treatment of vasopressin-sensitive cranial diabetes insipidus and in the treatment of post-hypophysectomy polyuria/polydipsia. In patients for whom desmopressin is an appropriate choice of therapy, it offers a sublingual formulation at an equivalent cost to a clinically equivalent dose in a solid oral dose formulation.	New formulation of a drug already included in the Formulary. FC October 2007
10.07.06 *SMC Report No. 282/06* PRODUCT UPDATE (abbreviated submission)	desmopressin 120micrograms oral lyophilisate (DesmoMelt®) *Ferring Pharmaceuticals Ltd* *Treatment of primary nocturnal enuresis.*	Accepted for use: desmopressin 120micrograms oral lyophilisate (DesmoMelt®) is accepted for use within NHS Scotland for the treatment of primary nocturnal enuresis. At clinically equivalent doses there is no additional cost for the sublingual formulation compared with conventional tablets.	Added to the LJF as first choice for use in primary nocturnal enuresis. FC April 2007

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
07.05.07 *SMC Report No. 357/07* PRODUCT UPDATE (abbreviated submission)	desmopressin 240micrograms oral lyophilisate (DesmoMelt®) *Ferring Pharmaceuticals Ltd* *Treatment of primary nocturnal enuresis.*	Accepted for use: desmopressin 240micrograms oral lyophilisate (DesmoMelt®) is accepted for use in NHS Scotland for the treatment of primary nocturnal enuresis. In patients for whom desmopressin oral lyophilisate is an appropriate choice of therapy, it offers a higher dose formulation at an equivalent cost to existing formulations.	Added to the LJF as first choice for use in primary nocturnal enuresis. FC April 2007
08.09.03 *SMC Report No. 36/03* RESUBMISSION	desogestrel (Cerazette®) *Organon Laboratories* *Contraception.*	Restricted use: desogestrel is now available as a progestogen-only contraceptive pill (POP), which has been shown to inhibit ovulation to a substantially greater extent than other POPs. Its use should be restricted to those individuals who cannot tolerate oestrogen containing contraceptives or in whom those preparations are contraindicated.	Approved for use - added to the Additional List. Cerazette® is a new POP and has been shown to inhibit ovulation more than other POPs but is more expensive. The first choice POPs in the Formulary are Micronor® and Noriday®. FC November 2003
11.06.12 *SMC Report No. 652/10* 2nd RESUBMISSION	dexamethasone 700 microgram intravitreal implant (Ozurdex®) *Allergan Ltd* *Treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion.*	Restricted use: dexamethasone intravitreal implant (Ozurdex®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion. SMC restriction: for use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment. In two phase III studies dexamethasone 700 microgram intravitreal implant was superior to sham administration at day 90 for the proportion of patients with a best corrected visual acuity improvement of ≥15 letters. Longer-term effectiveness of treatment is uncertain.	**Included** on the Additional List, Specialist Use only, for the treatment of patients with BRVO who are not suitable for laser therapy. **Not included** on the LJF, pending protocol, for the treatment of patients with CRVO. FC August 2012
16.01.12 *SMC Report No. 751/11* NON SUBMISSION	dexamethasone (Ozurdex®) 0.7 mg intravitreal implant *Allergan* *Treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.*	NOT RECOMMENDED: dexamethasone (Ozurdex®) 0.7 mg intravitreal implant is not recommended for use within NHS Scotland for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.06.12 *SMC Report No. 784/12*	dexmedetomidine 100 micrograms/mL concentrate for solution for infusion (Dexdor®) *Orion Pharma UK* *For sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3).*	Accepted for use: dexmedetomidine (Dexdor®) is accepted for use within NHS Scotland for sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3). Dexmedetomidine was as effective as propofol and midazolam in maintaining the target depth of sedation in ICU patients. The median duration of mechanical ventilation was numerically shorter with dexmedetomidine than with propofol and significantly shorter than with midazolam.	**Included** on the Additional List, Specialist Use only for the indication in question. FC October 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.11.07 *SMC Report No. 419/07* NON SUBMISSION	dexrazoxane (Cardioxane®) *Novartis Pharmaceuticals UK Ltd* *Prevention of chronic cumulative cardiotoxicity caused by doxorubicin or epirubicin use in advanced and/or metastatic cancer patients after previous anthracycline containing treatment.*	NOT RECOMMENDED: dexrazoxane (Cardioxane®) is not recommended for use within NHSScotland for the prevention of chronic cumulative cardiotoxicity caused by doxorubicin or epirubicin use in advanced and/or metastatic cancer patients after previous anthracycline containing treatment. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.10.08 *SMC Report No. 361/07* RESUBMISSION	dexrazoxane 20mg/mL, for infusion (Savene®) *TopoTarget A/S* *Treatment of anthracycline extravasation.*	NOT RECOMMENDED: dexrazoxane (Savene®) is not recommended for use within NHS Scotland for the treatment of anthracycline extravasation. Data from non-comparative, open-label phase II/III studies indicate that administration of dexrazoxane is associated with a relatively low rate of surgery and adverse sequelae following extravasation of anthracyclines. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC and in addition the justification of the treatment's cost in relation to its health benefits was not sufficient.	NOT RECOMMENDED
07.05.07 *SMC Report No. 365/07*	dibotermin alfa (recombinant human bone morphogenetic protein-2/absorbable collagen sponge; rhBMP-2/ACS), 12mg kit for implant (InductOs®) *Medtronic* *Treatment of acute tibia fractures in adults, as an adjunct to standard care using open fracture reduction and intramedullary nail fixation in patients in whom there is a substantial risk of non-union.*	Restricted use: dibotermin alfa (InductOs®) is accepted for restricted use within NHS Scotland for the treatment of acute tibia fractures in adults, as an adjunct to standard care using open fracture reduction and intramedullary nail fixation in patients in whom there is a substantial risk of non-union. It is restricted to patients treated with unreamed intramedullary nails. Cost effectiveness has only been shown in Gustilo-Anderson Grade IIIB fractures.	Added to the Additional List – Specialist Use only - to be used in unreamed open tibial fractures Gustilo-Anderson grade IIIB FC June 2008
07.11.05 *SMC Report No. 199/05*	diclofenac 1% gel patches (Voltarol Gel Patch®) *Novartis* *Local symptomatic treatment of pain in epicondylitis and ankle sprain.*	NOT RECOMMENDED: Diclofenac 1% gel patch (Voltarol Gel Patch®) is not recommended for use within NHS Scotland for the local symptomatic treatment of pain in epicondylitis and ankle sprain. Diclofenac gel patch provides analgesia similar to that obtained with a topical gel formulation of this drug. However, on a gram per gram basis, patches cost over 40% more than the gel formulation.	NOT RECOMMENDED
10.03.08 *SMC Report No. 446/08*	diclofenac, 75mg/2ml of solution for intravenous injection (Dyloject®) *Javelin Pharmaceuticals UK Limited* *By the intravenous route, treatment or prevention of post-operative pain in supervised healthcare settings.*	Restricted use: diclofenac (Dyloject ®) is accepted for restricted use within NHS Scotland for the treatment or prevention of post-operative pain by intravenous injection, in supervised health-care settings. When given as an intravenous bolus, it showed non-inferiority to a comparator non-steroidal anti-inflammatory drug infusion at providing pain relief over an initial 4 hour period and caused less thrombophlebitis. The manufacturer's submission related only to intravenous use of diclofenac (Dyloject ®) in the post-operative setting. SMC cannot recommend its use by the intramuscular route.	'Not preferred' in Lothian as suitable alternatives exist. FC November 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.12.10 *SMC Report No. 667/10* NON SUBMISSION	diclofenac 4% spray gel (Mobigel Spray ®) *Goldshield Group Plc* *Local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures.*	NOT RECOMMENDED: diclofenac 4% spray gel (Mobigel Spray ®) is not recommended for use within NHS Scotland. Indication under review: for the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.04.14 *SMC Report No. 886/13* Patient Access Scheme	dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®) *Biogen Idec Ltd* *Treatment of adult patients with relapsing remitting multiple sclerosis.*	Accepted for use: dimethyl fumarate (Tecfidera®) is accepted for use within NHS Scotland for treatment of adult patients with relapsing remitting multiple sclerosis. Two phase III, placebo-controlled studies demonstrated significantly superior efficacy for dimethyl fumarate compared to placebo for the primary end-points of proportion of patients relapsed at two years (in one study) and the annualised relapse rate (in the other study). This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dimethyl fumarate. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC May 2014
10.07.06 *SMC Report No. 283/06* PRODUCT UPDATE (abbreviated submission)	dinoprostone 10mg vaginal delivery system (Propess®) *Ferring Pharmaceuticals Ltd* *Initiation of cervical ripening in patients at term (from 38th week of gestation).*	Accepted for use: dinoprostone 10mg vaginal delivery system (Propess®) is accepted for use in NHS Scotland for initiation of cervical ripening in patients at term (from 38th week of gestation). This formulation replaces a product which released 5mg over 12 hours from a different 10mg vaginal delivery system. The new pessary formulation can remain in place for up to 24 hours where necessary and the cost per pessary is unchanged.	'Not preferred' in Lothian for initiation of cervical ripening in patients at term (from 38th week of gestation). FC September 2006
09.05.03 *SMC Report No. 42/03*	docetaxel (Taxotere®) *Aventis* *First-line treatment of non-small-cell lung cancer (NSCLC).*	Restricted use: docetaxel, in combination with cisplatin, is an effective treatment option for the first line treatment of unresectable, locally advanced or metastatic (stage III/IV) non-small cell lung cancer (NSCLC). In common with the other drugs recommended by Quality Improvement Scotland (QIS) for this condition, benefit has only been proven in patients with good performance status. Estimated cost per quality adjusted life year (QALY) gained is relatively high. Docetaxel should be initiated by respiratory physicians/oncologists experienced in the treatment of NSCLC.	**Included** in Formulary.
13.11.06 *SMC Report No. 333/06* NON SUBMISSION	docetaxel (Taxotere®) injection concentrate *Sanofi-Aventis UK* *In combination with cisplatin and 5-fluorouracil for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.*	NOT RECOMMENDED: docetaxel (Taxotere®) injection concentrate in combination with cisplatin and 5-fluorouracil is not recommended for use within NHSScotland for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.05.07 *SMC Report No. 369/07*	docetaxel 20 and 80mg concentrate and solvent for solution for infusion (Taxotere®) *Sanofi-Aventis* *Induction treatment of patients with unresectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.*	Restricted use: docetaxel (Taxotere®) is accepted for restricted use within NHS Scotland for the induction treatment of patients with unresectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil. It is restricted to patients in whom induction chemotherapy is appropriate. The docetaxel-containing induction regimen was associated with improved progression-free and overall survival, compared with cisplatin and 5-fluorouracil alone, in patients with good performance status.	Added to the Additional List, for Specialist Use only. FC July 2007
10.10.05 *SMC Report No. 201/05*	docetaxel 20mg, 80mg concentrate and solvent for solution for infusion, single dose vials (Taxotere®) *Sanofi-Aventis* *In combination with doxorubicin and cyclophosphamide for the adjuvant treatment of operable, node-positive breast cancer*	Accepted for use: docetaxel (Taxotere®) is accepted for use within NHS Scotland in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of operable, node-positive breast cancer. Docetaxel in combination with doxorubicin and cyclophosphamide was associated with a significant improvement in disease free survival at 5 years when compared with one of the standard treatment regimens. However, this benefit is associated with an increased risk of toxicity. Docetaxel has demonstrated cost effectiveness in comparison to standard treatment regimen used in NHS Scotland.	Added to the Formulary, for Specialist Use only. FC November 2005
07.11.05 *SMC Report No. 209/05*	docetaxel concentrate and solvent for solution for infusion, single dose vials (Taxotere®) *Sanofi-Aventis* *New indication: treatment of hormone refractory metastatic prostate cancer.*	SMC - not recommended for use. NICE - recommends for use, within its licensed indications (NICE technology appraisal guidance 101. Docetaxel for the treatment of hormone-refractory metastatic prostate cancer. June 2006. www.nice.org.uk/page.aspx?o=TA101) NHS QIS www.nhshealthquality.org/nhsqis advises that this NICE appraisal supersedes the advice issued by the Scottish Medicines Consortium 7 November 2005.	Added to the LJF as first choice, for Specialist Use only. FC January 2007
07.07.08 *SMC Report No 481/08*	docetaxel 20 and 80mg concentrate and solvent for solution for infusion (Taxotere®) *Sanofi-aventis* *For the induction treatment of patients with resectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.*	Restricted use: accepted for restricted use within NHS Scotland for the induction treatment of patients with resectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil. It is restricted to patients in whom induction chemotherapy is appropriate. In the pivotal study, which included patients with technically resectable disease, the docetaxel-containing induction regimen was associated with improved overall survival compared with cisplatin and 5-fluorouracil alone. SMC has previously issued advice for patients with unresectable disease and this now extends the advice to patients with resectable disease.	Added to the Additional List, Specialist Use only. FC May 2009
08.11.10 *SMC Report No. 659/10* NON SUBMISSION	docetaxel (Taxotere®) 20 mg/1ml and 80 mg/4ml and 160 mg/8ml concentrate for solution for infusion *Sanofi Aventis* *Adjuvant treatment of patients with operable node-negative breast cancer.*	NOT RECOMMENDED: docetaxel (Taxotere®) in combination with doxorubicin and cyclophosphamide is not recommended for use within NHS Scotland. Indication under review: adjuvant treatment of patients with operable node-negative breast cancer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result SMC cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.05.14 *SMC Report No. 961/14* Patient Access Scheme	dolutegravir 50mg film-coated tablets (Tivicay®) *ViiV Healthcare/GlaxoSmithKline* *In combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age.*	Accepted for use: dolutegravir (Tivicay®) is accepted for use within NHS Scotland in combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age. In phase III clinical studies, dolutegravir has demonstrated non-inferiority or superiority to three comparator antiretroviral medicines in treatment-naïve adults with HIV, and superiority to an alternative integrase inhibitor in treatment-experienced adults. (All study patients also received two nucleoside reverse-transcriptase inhibitors). This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of dolutegravir. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**For adults:** **Included** on the Additional List, for Specialist Use only, for the indication in question. FC May 2014 **For adolescents above 12 years of age:** Formulary classification not yet decided – waiting for information from clinician.
26.02.07 *SMC Report No. 307/06* PRODUCT UPDATE (abbreviated submission)	donepezil 5mg and 10mg orodispersible tablets (Aricept® Evess) *Eisai Ltd* *Symptomatic treatment of mild to moderately severe Alzheimer's dementia in patients for whom donepezil is appropriate and who have difficulty in swallowing solid oral dose formulations.*	Accepted for use: donepezil orodispersible tablet (Aricept Evess®) is accepted for use within NHS Scotland for the symptomatic treatment of mild to moderately severe Alzheimer's dementia in patients for whom donepezil is appropriate and who have difficulty in swallowing solid oral dose formulations. It costs the same as standard formulations of donepezil.	New formulation of a drug already included in the Formulary. FC October 2007
09.02.09 *SMC Report No. 529/09*	doripenem 500mg powder for solution for infusion (Doribax®) *Janssen Cilag* *Treatment of complicated intra-abdominal infections in adults.*	Restricted use: doripenem (Doribax®) is accepted for restricted within NHS Scotland for the treatment of complicated intra-abdominal infections in adults. In patients with complicated intra-abdominal infection, doripenem is associated with clinical cure rates non-inferior to those of another carbapenem. Doripenem should be restricted to use as a second or third-line treatment of complicated intra-abdominal infections resistant to current conventional treatments. It should be used only on the advice of local microbiologists or specialists in infectious diseases.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010
09.03.09 *SMC Report No. 539/09*	doripenem, 500mg powder for solution for infusion (Doribax®) *Janssen-Cilag* *Treatment of nosocomial pneumonia (including ventilator-associated pneumonia) in adults.*	Restricted use: doripenem (Doribax®) is accepted for restricted use within NHS Scotland for the treatment of nosocomial pneumonia (including ventilator-associated pneumonia) in adults. Doripenem demonstrated similar clinical cure rates to other drugs used for the treatment of nosocomial pneumonia (including ventilator-associated pneumonia). It is an alternative option to existing carbapenems and should only be used on the advice of local microbiologists or specialists in infectious diseases. Doripenem is also licensed for the treatment of complicated urinary tract infections in adults. As the manufacturer has not made a submission for this indication, SMC cannot recommend the use of doripenem in the treatment of complicated urinary tract infections in adults.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010
12.06.06 *SMC Report No. 238/06* PRODUCT UPDATE (abbreviated submission)	dorzolamide 2% preservative-free unit dose eye drops (Trusopt®) *Merck Sharp & Dohme* *Treatment of elevated intra-ocular pressure in ocular hypertension, open-angle glaucoma and pseudo-exfoliative glaucoma.*	Restricted use: dorzolamide 2% preservative-free unit-dose eye drops (Trusopt®) are accepted for restricted use in NHS Scotland for the treatment of elevated intra-ocular pressure in ocular hypertension, open-angle glaucoma and pseudo-exfoliative glaucoma. They are licensed as adjunctive therapy to beta-blockers and as monotherapy in patients unresponsive to beta-blockers or in whom beta-blockers are contra-indicated. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation and should be restricted to use in patients for whom dorzolamide is appropriate and who have proven sensitivity to the preservative benzalkonium chloride.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
11.12.06 *SMC Report No. 293/06* PRODUCT UPDATE (abbreviated submission)	dorzolamide 2% / timolol maleate 0.5% preservative-free unit dose eye drops (COSOPT®) *Merck Sharpe & Dohme* *Treatment of elevated intra-ocular pressure in patients with open-angle glaucoma and pseudo-exfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.*	Restricted use: dorzolamide / timolol preservative-free unit-dose eye drops (COSOPT®) are accepted for restricted use in NHS Scotland for the treatment of elevated intra-ocular pressure in patients with open-angle glaucoma and pseudo-exfoliative glaucoma when topical beta-blocker monotherapy is not sufficient. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation and should be restricted to use in patients for whom a combination of these two agents is appropriate and who have proven sensitivity to the preservative benzalkonium chloride.	**Included** on the Additional List, for Specialist Initiation, for the indication in question. FC April 2014
13.09.10 *SMC Report No. 636/10*	dronedarone, 400mg, film-coated tablets (Multaq®) *Sanofi-aventis Ltd* *Dronedarone is indicated in adult clinically stable patients with a history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate.*	Restricted use: dronedarone (Multaq®) is accepted for restricted use within NHS Scotland. Indication under review: in adult clinically stable patients with a history of, or current nonpermanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate. SMC restriction: for the prevention of recurrence of AF in patients in whom beta-blockers, class 1c drugs or amiodarone are contra-indicated, ineffective or not tolerated. Treatment should be initiated on specialist advice only. Dronedarone appears less effective than amiodarone in reducing atrial fibrillation recurrence but has the potential for improved tolerability compared to comparator medicines.	Added to the Additional List, Specialist initiation. FC November 2010
04.10.02 *SMC Report No. 13/02*	drotrecogin alfa [activated] (Xigris®) *Eli Lilly* *Treatment of patients with severe sepsis with multiple-organ failure.*	Restricted use: drotrecogin alfa [activated] is a significant advance in the treatment of patients with severe sepsis with multiple-organ failure. It supplements the existing treatment strategies of infection eradication and support for failing organs/systems. When added to the best standard care of patients with severe sepsis it significantly reduces mortality in the most severely ill patients, i.e. those with more than one new failing organ/system and/or those with an APACHE II score >25. A register of recipients of this preparation should be established and maintained to provide additional information about its effectiveness and safety in the clinical setting.	Approved for use - added to the Additional List. FC May 2003
11.10.04 *SMC Report No. 119/04*	duloxetine (Yentreve®) *Eli Lilly and Company* *Treatment of moderate to severe stress urinary incontinence (SUI).*	Restricted use: duloxetine is accepted for restricted use within NHS Scotland for the treatment of moderate to severe stress urinary incontinence (SUI). It should be used only as part of an overall management strategy for SUI in addition to pelvic floor muscle training. Patients should be reviewed after 12 weeks of therapy to assess progress and determine whether it is appropriate to continue treatment. Because of the short duration of treatment in the studies supplied, it is recommended that the manufacturers collect further data on the long-term effects of this pharmacological approach to the management of SUI.	Added to the LJF as second choice treatment for moderate to severe stress incontinence. First choice treatment is pelvic floor muscle exercises. Until such time as further evidence is available on safety, efficacy and cost effectiveness, the prescribing of duloxetine should only be initiated in secondary care. FC May 2005
12.09.05 *SMC Report No. 195/05*	duloxetine 30mg, 60mg capsules (Cymbalta®) *Eli Lilly & Co Ltd/Boehringer Ingelheim* *Treatment of major depressive episodes in accordance with existing guidelines (i.e. in patients who have not responded to or are unable to tolerate initial treatment options).*	Restricted use: duloxetine (Cymbalta®) is accepted for restricted use within NHS Scotland for the treatment of major depressive episodes in accordance with existing guidelines (i.e. in patients who have not responded to or are unable to tolerate initial treatment options). On the basis of the limited comparative data available, duloxetine appears to offer similar efficacy to other antidepressants in this treatment position at a similar cost.	Added to the Additional List. FC March 2007

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11.09.06 *SMC Report No. 285/06*	duloxetine 30mg and 60mg capsules (Cymbalta®) *Eli Lilly and Company Limited/Boehringer Ingelheim* *Treatment of diabetic peripheral neuropathic pain in adults.*	Restricted use: duloxetine (Cymbalta®) is accepted for restricted use for the treatment of diabetic peripheral neuropathic pain in adults. Duloxetine relieved peripheral neuropathic pain compared with placebo in patients with diabetes. It is restricted to initiation by prescribers experienced in the management of diabetic peripheral neuropathic pain as 2nd or 3rd line therapy.	Added to the LJF as a Prescribing Note. FC November 2008
13.10.08 *SMC Report No. 514/08* NONSUBMISSION	duloxetine (Cymbalta®) 30mg & 60 mg hard gastro-resistant capsules *Eli Lilly and Company Limited* *For the treatment of generalised anxiety disorder.*	NOT RECOMMENDED: duloxetine (Cymbalta®) is not recommended for use within NHS Scotland for the treatment of generalised anxiety disorder. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
09.05.03 *SMC Report No. 37/03*	dutasteride (Avodart®) *GlaxoSmithKline* *Benign prostatic hyperplasia*	Accepted for use: dutasteride has demonstrated similar efficacy and safety to alternative 5a-reductase inhibitors in reducing prostate volume in patients with BPH. Dutasteride is likely to be cost-neutral to NHS Scotland in the treatment of BPH.	Added to the Additional List FC January 2004 and FC January 2006
09.08.10 *SMC Report No 628/10* PRODUCT UPDATE (abbreviated submission)	dutasteride 0.5mg plus tamsulosin 0.4mg capsule (Combodart®) *GlaxoSmithKline* *Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH); Reduction in the risk of acute urinary retention and surgery in patients with moderate to severe symptoms of BPH.*	Accepted for use: dutasteride plus tamsulosin (Combodart®) is accepted for use within NHS Scotland. Indications under review: Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH); Reduction in the risk of acute urinary retention and surgery in patients with moderate to severe symptoms of BPH. In patients for whom concomitant use of these medicines is appropriate, this combination allows administration of a single capsule at reduced cost compared to the individual components	Added to the Additional List when the combination of these medicines is deemed appropriate. FC August 2010
08.11.10 *SMC Report No. 436/07*	eculizumab 300mg concentrate for solution for infusion (Soliris®) *Alexion Pharma UK Ltd* *For the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of eculizumab in the treatment of patients with PNH is limited to patients with a history of transfusions.*	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland. Indication under review: for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of eculizumab in the treatment of patients with PNH is limited to patients with a history of transfusions. In a controlled study in patients with transfusion-dependent PNH, eculizumab reduced the rate of haemolysis and improved anaemia compared to placebo. Uncontrolled data suggest that eculizumab reduces the incidence of thrombosis in patients with PNH. The manufacturer did not supply any health economic analysis and cost-effectiveness was not demonstrated in an independent economic analysis therefore eculizumab cannot be recommended for use within NHS Scotland.	NOT RECOMMENDED
13.02.12 *SMC Report No. 767/12* NON SUBMISSION	eculizumab (Soliris®) 300 mg concentrate for solution for infusion *Alexion Pharma UK Ltd* *Treatment of patients with atypical haemolytic uremic syndrome (aHUS).*	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland for the treatment of patients with atypical haemolytic uremic syndrome (aHUS). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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09.09.13 *SMC Report No. 915/13* NON SUBMISSION	eculizumab (Soliris®) 300 mg concentrate for solution for infusion *Alexion Pharma UK Ltd* *In children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH).*	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland in children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.02.05 *SMC Report No. 146/04*	efalizumab (Raptiva®) 125 mg as powder and solvent for 100mg/ml injection *Genentech, in partnership with Serono. Developed by XOMA.* *Treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or have a contra-indication to, or are intolerant to other systemic therapies, including ciclosporin, methotrexate and PUVA (photochemotherapy).*	SMC - not recommended for use. NICE - recommends for use (NICE technology appraisal guidance 103. Etanercept and efalizumab for adults with psoriasis. July 2006. www.nice.org.uk/page.aspx?o=TA103) NHS QIS www.nhshealthquality.org/nhsqis advises that this NICE appraisal is as valid for Scotland as for England and Wales and that the guidance on efalizumab supersedes the advice issued by the Scottish Medicines Consortium 10 December 2004.	Added to the Additional List, for Specialist Use only. FC October 2006 **Marketing authorisiation withdrawn** **FC April 2009**
07.04.08 *SMC Report No. 442/08* PRODUCT UPDATE (abbreviated submission)	efavirenz 600mg, emtricitabine 200mg, tenofovir disoproxil 245mg as fumarate (Atripla®) *Bristol Myers Squibb/Gilead Sciences/Merck Sharp & Dohme Ltd* *Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with virologic suppression to HIV-1 RNA levels of < 50 copies/ml on their current combination antiretroviral therapy for more than three months.*	Accepted for use: efavirenz is accepted for use in NHS Scotland for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with virologic suppression to HIV-1 RNA levels of < 50 copies/ml on their current combination antiretroviral therapy for more than three months. Patients must not have experienced virological failure on any prior antiretroviral therapy and must be known not to have harboured virus strains with mutations conferring significant resistance to any of the three components contained in this fixed dose combination prior to initiation of their first antiretroviral treatment regimen. It may be used to simplify the regimen of patients for whom this combination is indicated (see above) and in whom all three agents are appropriate components at the doses provided by this fixed dose combination.	New formulation of drugs already in the Formulary. FC April 2008
12.09.05 *SMC Report No. 159/05* RESUBMISSION	eflornithine 11.5% cream (Vaniqa®) *Shire Pharmaceutical Contracts Ltd* *Facial hirsutism.*	Restricted use: eflornithine 11.5% cream (Vaniqa®) is accepted for restricted use within NHS Scotland for the treatment of facial hirsutism in women. It is restricted to use in women for whom alternative drug therapy is ineffective, contra-indicated or considered inappropriate. Eflornithine 11.5% cream, as a topical treatment, may offer advantages over existing therapy for some women as it avoids the risks associated with systemic therapies.	'Not preferred' in Lothian for the treatment of facial hirsutism in women - pending additional information from clinicians, requested by FC. FC July 2006

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.08.10 *SMC Report No. 625/10*	eltrombopag, 25mg and 50mg film-coated tablets (Revolade®) *GlaxoSmithKline UK* *For adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Eltrombopag may be considered as second-line treatment for adult non splenectomised patients where surgery is contraindicated.*	Restricted use: eltrombopag (Revolade®) is accepted for restricted use within NHS Scotland. Indication under review: Eltrombopag is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Eltrombopag may be considered as second-line treatment for adult non splenectomised patients where surgery is contraindicated. SMC restriction: in both the splenectomised and non-splenectomised patient populations, restricted to use in patients with severe symptomatic ITP or a high risk of bleeding. Eltrombopag has been shown to be significantly more effective than placebo in raising and maintaining platelet counts at (or above) a minimum target level in previously treated patients with ITP.	Added to the Additional List, for Specialist Use only. FC November 2011
09.12.13 *SMC Report No. 919/13* Patient Access Scheme	eltrombopag, 25mg, 50mg, 75mg film-coated tablets (Revolade®) *GlaxoSmithKline* *In adult patients with chronic hepatitis C virus infection, for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.*	Accepted for use: eltrombopag (Revolade®) is accepted for use within NHS Scotland in adult patients with chronic hepatitis C virus infection, for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. Two double-blind, randomised, controlled studies in patients with chronic hepatitis C virus infection and thrombocytopenia demonstrated significantly higher sustained viral response rates in patients who continued treatment with eltrombopag during interferon-based antiviral therapy than in those patients whose eltrombopag treatment was discontinued on initiation of antiviral therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eltrombopag. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. A treatment protocol has been requested from the clinical team. FC February 2014
12.08.13 *SMC Report No. 887/13* Patient Access Scheme	elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg film coated tablet (Stribild®) *Gilead Sciences Ltd* *Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®.*	Accepted for use: elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil (as fumarate) film coated tablet (Stribild®) is accepted for use within NHS Scotland. Indication under review: treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®. Stribild® was at least as effective as two other recommended antiretroviral regimens in treatment-naïve HIV-1 infected patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Stribild®. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC October 2013

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.02.06 *SMC Report No. 105/04* RESUBMISSION	emtricitabine 200mg hard capsules (Emtriva®) *Gilead Sciences International* *Treatment of HIV-1 infected adults in combination with other antiretroviral agents.*	Accepted for use: emtricitabine (Emtriva®) is accepted for use within NHS Scotland for the treatment of HIV-1 infected adults in combination with other antiretroviral agents. It should be prescribed only by HIV specialists. This indication is based on studies in treatment-naïve patients and treatment-experienced patients with stable virological control in whom, as part of antiretroviral therapy (ART) regimens, it has shown virological responses comparable with other ART. There is no experience of use in patients who are failing their current regimen or who have failed multiple regimens.	Approved for use - added to the Additional List. FC April 2006
13.02.06 *SMC Report No. 237/06* PRODUCT UPDATE (abbreviated submission)	emtricitabine / tenofovir disoproxil 200mg/245mg tablet (Truvada®) *Gilead Sciences Ltd* *Treatment of HIV-1 infected adults in combination with other antiretroviral medicinal products.*	Accepted for use: emtricitabine/tenofovir disoproxil 200mg/245mg tablet (Truvada®) is accepted for use in NHS Scotland for the treatment of Human Immunodeficiency Virus (HIV-1) infected adults in combination with other antiretroviral medicinal products. Both constituents are nucleoside reverse transcriptase inhibitors. The demonstration of the benefit of the combination emtricitabine and tenofovir disoproxil fumarate in antiretroviral therapy is based solely on studies performed in treatment-naïve patients.	Added to the Formulary as second choice, for Specialist Use only. For use only in treatment-naïve patients known to be abacavir intolerant. FC May 2006
13.02.12 *SMC Report No. 759/12* PRODUCT UPDATE (abbreviated submission)	emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) *Gilead Sciences Limited* *Treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.*	Accepted for use: emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) is accepted for use in NHS Scotland for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml. As with other antiretroviral therapies, genotypic resistance testing should inform the use of Eviplera®. This combination tablet has been shown to be bioequivalent to the individual components given separately. It is available at pro rata cost to the individual components and may be used to simplify the regimen of patients for whom this combination of HIV therapies is appropriate at the doses provided in this fixed dose combination.	Added to the Additional List for Specialist Use only. **Included** on the Lothian Joint Formulary for the indication in question. FC April 2012
11.08.03 *SMC Report No. 56/03*	enfuvirtide (Fuzeon®) *Roche* *In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients who have received treatment with and failed on regimens containing at least one medicinal product from each of the following antiretroviral classes, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors, or who have intolerance to previous antiretroviral regimens.*	Restricted use: enfuvirtide (Fuzeon®) is restricted to use by clinicians experienced in the management of HIV infected patients. It is licensed for use in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients who have received treatment with and failed on regimens containing at least one medicinal product from each of the following antiretroviral classes, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors, or who have intolerance to previous antiretroviral regimens.	Approved for use - added to the Additional List. FC September 2003

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.07.09 *SMC Report No. 380/07*	enoxaparin 20mg, 40mg, 60mg, 80mg, 100mg 120mg and 150mg pre-filled syringes and 300mg multidose vial (Clexane®) *Sanofi-aventis* *Treatment of acute ST-segment Elevation Myocardial Infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI) in conjunction with thrombolytic drugs (fibrin or non-fibrin specific).*	Accepted for use: enoxaparin (Clexane®) is accepted for use within NHS Scotland for the treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI) in conjunction with thrombolytic drugs (fibrin or non-fibrin specific). In clinical studies using a median of seven days of enoxaparin treatment, enoxaparin demonstrated a reduction in death or non-fatal MI compared to unfractionated heparin.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010
09.10.06 *SMC Report No. 320/06*	entecavir, 0.5 and 1mg tablets (Baraclude®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *Treatment of chronic hepatitis B virus infection in adults with compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and or fibrosis.*	Accepted for use: entecavir (Baraclude®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and or fibrosis. Clinical studies have shown that entecavir is more effective than lamivudine in nucleoside-naïve HBeAg positive and negative patients and in lamivudine refractory patients.	Added to the Additional List. Treatment to be initiated in secondary care for 1 month, thereafter prescribing to be continued in primary care under a shared care protocol. FC December 2007
16.01.12 *SMC Report No. 747/11*	entecavir, 0.5mg and 1mg film-coated tablets and 0.05 mg/mL oral solution (Baraclude®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *For the treatment of chronic hepatitis B virus (HBV) infection in adults with decompensated liver disease.*	NOT RECOMMENDED: entecavir (Baraclude®) is not recommended for use within NHS Scotland for the treatment of chronic hepatitis B virus (HBV) infection in adults with decompensated liver disease. Entecavir demonstrated a superior virological response in adults with chronic HBV and decompensated liver disease compared with another nucleoside/nucleotide analogue. However there is no comparative evidence versus the relevant comparator. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
11.11.13 *SMC Report No. 911/13* Patient Access Scheme	enzalutamide 40mg soft capsules (Xtandi®) *Astellas Pharma Ltd* *Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy.*	Accepted for use: enzalutamide (Xtandi®) is accepted for use within NHS Scotland for the treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy. In one randomised, double-blind, phase III clinical study, enzalutamide significantly increased overall survival compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of enzalutamide. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC December 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.05.06 *SMC Report No. 267/06* NON SUBMISSION	epinastine (Relestat®) 0.5 mg/ml, eye drops, solution *Allergen Ltd* *Treatment of the symptoms of seasonal allergic conjunctivitis.*	NOT RECOMMENDED: epinastine (Relestat®) is not recommended for use within NHSScotland for the treatment of the symptoms of seasonal allergic conjunctivitis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.05.05 *SMC Report No. 136/04* RESUBMISSION	eplerenone 25mg and 50mg tablets (Inspra®) *Pfizer Ltd* *In addition to standard therapy including beta blockers, to reduce the risk of cardiovascular mortality and morbidity between 3-14 days after myocardial infarction (MI) in stable patients with left ventricular dysfunction (left ventricular ejection fraction £40%) and clinical evidence of heart failure.*	Accepted for use: eplerenone (Inspra®) is accepted for use within NHS Scotland in addition to standard therapy including beta blockers, to reduce the risk of cardiovascular mortality and morbidity between 3-14 days after myocardial infarction (MI) in stable patients with left ventricular dysfunction (left ventricular ejection fraction £40%) and clinical evidence of heart failure. Eplerenone is the second aldosterone antagonist marketed in the UK. It reduces all-cause mortality and cardiovascular-related mortality and hospitalisation in patients with left ventricular dysfunction and clinical evidence of heart failure after an MI. There are no data on its clinical and cost effectiveness in patients with chronic heart failure compared to the other aldosterone antagonist marketed in the UK, which reduces mortality and morbidity in patients with chronic heart failure and is considerably cheaper.	Added to the Formulary as a Prescribing Note. To be initiated in secondary care and continued in primary care, following MI in patients with left ventricular dysfunction and clinical evidence of heart failure (unless the patient is diabetic) who cannot tolerate spironolactone. This differs slightly from the SMC advice in that it includes diabetic patients with no clinical evidence of heart failure. FC September 2005
09.07.12 *SMC Report No. 793/12*	eplerenone 25, 50mg film-coated tablets (Inspra®) *Pfizer Ltd* *In addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%).*	Accepted for use: eplerenone (Inspra®) is accepted for use within NHS Scotland in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%). In the pivotal phase IIIb study, addition of eplerenone to standard optimal therapy significantly reduced the composite of death from cardiovascular causes or hospitalisation for heart failure (primary outcome) and both the risk of cardiovascular death and the risk of hospitalisation (secondary outcomes) in patients with mild heart failure (NYHA class II) and LVEF ≤30%.	**Included** on the LJF as a prescribing note for the treatment of NYHA class II patients only. FC October 2012
08.02.10 *SMC Report No. 597/10*	epoetin alfa 1,000 IU/0.5mL, 2,000 IU/1mL, 3,000 IU/0.3mL, 4,000 IU/0.4mL, 5,000 IU/0.5mL, 6,000 IU/0.6mL, 7,000 IU/0.7mL, 8,000 IU/0.8mL, 9,000 IU/0.9mL, 10,000 IU/1mL, solution for injection in prefilled syringe (Binocrit®) *Sandoz Ltd* *Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult and paediatric patients:* *Treatment of anaemia associated with CRF in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis.* *Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis.*	Accepted for use: epoetin alfa (Binocrit®) is accepted for use within NHS Scotland for: -treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients: -treatment of anaemia associated with chronic renal failure in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis; -treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis. Binocrit® can be used to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (haemoglobin 10 to 13g/dL [6.2 to 8.1 mmol/L], no iron deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more for males). Epoetin alfa (Binocrit®) is a biosimilar product and has demonstrated equivalency in terms of efficacy and safety to a reference product (epoetin alfa (Eprex®)). Unlike some other erythropoiesis stimulating agents, Binocrit® is only licensed for administration by the intravenous route in the indications under review. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2011

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.11.07 *SMC Report No. 418/07*	epoetin delta, for injection (Dynepo®) *Shire Pharmaceuticals Ltd* *Treatment of anaemia in patients with chronic renal failure.*	Accepted for use: epoetin delta (Dynepo®) is accepted for use within NHS Scotland for the treatment of anaemia in patients with chronic renal failure. It may be used in patients on dialysis and in patients not on dialysis. Clinical studies have demonstrated epoetin delta's efficacy and safety profile in correcting and maintaining haemoglobin levels for up to a year in predialysis, haemodialysis and peritoneal dialysis patients, when administered via both the subcutaneous and intravenous routes.	'Not preferred' as suitable alternatives exist. FC May 2009 PRODUCT WITHDRAWN FROM THE MARKET
12.07.10 *SMC Report No. 620/10*	epoetin theta, 1,000 IU/0.5mL, 2,000 IU/0.5mL, 3,000 IU/0.5mL, 4,000 IU/0.5mL, 5,000 IU/0.5mL, 10,000 IU/1mL, 20,000 IU/1mL, 30,000 IU/1mL solution for injection in pre filled syringe (Eporatio®) *Ratiopharm UK Limited* *Treatment of symptomatic anaemia associated with chronic renal failure in adult patients.*	Accepted for use within NHS Scotland for the treatment of symptomatic anaemia associated with chronic renal failure in adult patients. Epoetin theta demonstrated non-inferiority to another erythropoietin analogue in maintaining stable haemoglobin levels in renal failure associated anaemia both in patients not yet receiving dialysis (subcutaneous route) and in those receiving haemodialysis (intravenous route). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name. Other erythropoietin stimulating agents are available at lower cost.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC March 2012
09.06.08 *SMC Report No. 467/08*	epoetin zeta, 1000 IU/0.3ml, 2000 IU/0.6ml, 3000 IU/0.9ml, 4000 IU/0.4ml, 5000 IU/0.5ml, 6000 IU/0.6ml, 8000 IU/0.8ml, 10,000 IU/1.0ml, 20,000 IU/0.5ml, 30,000 IU/0.75ml and 40,000 IU/1ml solution for injection in pre-filled syringe (Retacrit®) *Hospira UK Limited* *Treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis and for treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis.*	Accepted for use: epoetin zeta (Retacrit®) is accepted for use within NHS Scotland for treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis and for treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis. Clinical studies in adult haemodialysis patients have demonstrated equivalence in correcting and maintaining haemoglobin levels when compared to another erythropoiesis stimulating agent (ESA). Unlike other ESAs, epoetin zeta is only licensed for administration by the intravenous route.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC November 2009
12.11.07 *SMC Report No. 415/07*	erdosteine 300mg capsules (Erdotin®) *Edmond Pharma Sr.l/Galen Ltd.* *As an expectorant for the symptomatic treatment of acute exacerbations of chronic bronchitis in adults.*	NOT RECOMMENDED: erdosteine (Erdotin®) is not recommended for use within NHS Scotland as an expectorant for the symptomatic treatment of acute exacerbations of chronic bronchitis in adults. Evidence for the clinical efficacy of erdosteine is limited and was obtained from studies that do not reflect current practice for the management of chronic obstructive pulmonary disease (COPD) in NHS Scotland. The manufacturer did not present a sufficiently robust clinical or economic case for erdosteine to gain acceptance by SMC.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.10.11 *SMC Report No. 726/11*	eribulin 0.44mg/mL solution for injection (Halaven®) *Eisai Ltd.* *Eribulin monotherapy is indicated for the treatment of patients with locally advanced breast cancer (LABC) or metastatic breast cancer (MBC) who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments.*	NOT RECOMMENDED: eribulin (Halaven®) is not recommended for use within NHS Scotland. eribulin monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments. In a randomised, phase III, open-label study eribulin-treated patients had 2.5 months additional survival compared to the comparator, treatment of physicians choice, which included a range of single agent chemotherapy treatments. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
09.07.07 *SMC Report No. 382/07* NON SUBMISSION	erlotinib (Tarceva®) *Roche Pharmaceuticals* *In combination with gemcitabine for the treatment of patients with metastatic pancreatic cancer.*	NOT RECOMMENDED: erlotinib (Tarceva®) in combination with gemcitabine is not recommended for use within NHSScotland for the treatment of patients with metastatic pancreatic cancer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.06.06 *SMC Report No. 220/05* RESUBMISSION	erlotinib, 100 and 150mg film-coated tablets (Tarceva®) *Roche* *Treatment of patients with locally advanced or metastatic non-small cell lung cancer, after failure of at least one prior chemotherapy regimen.*	Restricted use: erlotinib (Tarceva®) is accepted for restricted use within NHS Scotland for the treatment of patients with locally advanced or metastatic non-small cell lung cancer, after failure of at least one prior chemotherapy regimen. When prescribing erlotinib, factors associated with prolonged survival should be taken into account. No survival benefit or other clinically relevant effect of the treatment has been demonstrated in patients with epidermal growth factor receptor (EGFR)-negative tumours. Erlotinib is restricted to use in patients who would otherwise be eligible for treatment with docetaxel monotherapy. No economic case has been made for those whose performance status would make them ineligible to receive docetaxel.	Added to the Additional List, for Specialist Use only. FC September 2006
17.01.11 *SMC Report No. 664/10*	erlotinib, 25, 100 and 150mg film-coated tablets (Tarceva®) *Roche* *Monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy.*	NOT RECOMMENDED: erlotinib (Tarceva®) is not recommended for use within NHS Scotland. Indication under review: as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy. Erlotinib maintenance treatment provided a statistically significant increase in progression free survival and overall survival in patients treated with standard first-line platinum-based chemotherapy, both in the whole study population and in a post hoc analysis in patients with stable disease. In the whole study population the changes in these outcomes were considered to be of modest size. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
16.01.12 *SMC Report No. 749/11* Patient Access Scheme	erlotinib 25, 100 and 150mg film-coated tablets (Tarceva®) *Roche Products Ltd* *For first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations.*	Accepted for use: erlotinib (Tarceva®) is accepted for use within NHS Scotland for first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations. In patients with advanced or metastatic NSCLC with EGFR mutations, erlotinib was associated with significantly improved progression-free survival compared with platinum-based doublet chemotherapy regimens. There are no mature overall survival data. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of erlotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only. FC March 2012
13.12.04 *SMC Report No. 134/04*	ertapenem (Ivanz®) *Merck Sharpe & Dohme* *Treatment of intra-abdominal infections in adults*	Restricted use: ertapenem is accepted for restricted use within NHS Scotland for the treatment of intra-abdominal infections in adults. Ertapenem should only be used second or third line treatment of community acquired intra-abdominal infections resistant to the current conventional treatments and under the advice of local microbiologists or specialists in infectious diseases.	'Not preferred' as suitable alternatives exist. FC January 2005
07.08.06 *SMC Report No. 291/06* PRODUCT UPDATE (abbreviated submission)	ertapenem sodium infusion (Invanz®) Paediatric *Merck Sharpe & Dohme* *Treatment of intra-abdominal infections in children and adolescents.*	Restricted use: ertapenem is accepted for restricted use within NHS Scotland for the treatment of intra-abdominal infections in children and adolescents. Ertapenem should only be used second line for the treatment of the community acquired intra-abdominal infections resistant to the current conventional treatments and under the advice of local microbiologists or specialists in infectious diseases.	'Not preferred' as suitable alternatives exist. FC October 2007
15.01.07 *SMC Report No. 335/06*	ertapenem, 1g vial of powder for solution for intravenous infusion (Invanz®) *Merck Sharp & Dohme Ltd* *Treatment of diabetic foot infections of the skin and soft tissue when caused by bacteria known or very likely to be susceptible to ertapenem and where broad spectrum parenteral therapy is appropriate.*	Restricted use: ertapenem for intravenous infusion (Invanz®) is accepted for restricted use within NHS Scotland for the treatment of diabetic foot infections of the skin and soft tissue when caused by bacteria known or very likely to be susceptible to ertapenem and where broad spectrum parenteral therapy is appropriate. It is restricted to use by specialists managing diabetic foot infection or on the advice of a microbiologist. Ertapenem showed non-inferiority to a penicillin/beta-lactamase inhibitor combination in the pivotal trial. Although ertapenem has a greater acquisition cost than some treatment options, its once-daily dosing regimen may allow changes in service delivery that have individual patient or organisational benefits. Efficacy of ertapenem in the treatment of diabetic foot infection with concurrent osteomyelitis has not been established.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC June 2008.
08.10.07 *SMC Report No. 404/07*	ertapenem, 1g vial of powder for concentrate for solution for intravenous infusion (Invanz®) *Merck, Sharp & Dohme Limited* *Prophylaxis of surgical site infection following elective colorectal surgery in adults.*	Restricted use: ertapenem (Invanz®) is accepted for restricted use within NHS Scotland for the prophylaxis of surgical site infection following elective colorectal surgery in adults. It is effective in reducing the incidence of surgical site infection, although there are currently no comparisons with regimens used in Scotland. It is restricted to use in line with local antimicrobial policies and Microbiologist advice.	'Not preferred' as suitable alternatives exist. FC December 2008
07.03.03 *SMC Report No. 17/02* RESUBMISSION	escitalopram (Cipralex®) *Lundbeck Ltd* *Major depressive episodes.*	Accepted for use: escitalopram has been shown to be as effective as citalopram in short-term use and the health economic model submitted suggests that it is also cost-effective. However, the resource usage assumptions and clinical evidence underpinning the model are not robust and no clear benefits are demonstrated over the parent product - citalopram or other effective and cheaper agents.	Following a resubmission to the Formulary Committee, escitalopram remains 'Not preferred' in Lothian for the treatment of depression. FC March 2006

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.05.06 *SMC Report No. 253/06*	escitalopram 5mg, 10mg and 20mg tablets (Cipralex®) *Lundbeck Limited* *Treatment of generalised anxiety disorder in situations where pharmacological therapy is appropriate.*	Accepted for use: escitalopram (Cipralex®) is accepted for use within NHS Scotland for the treatment of generalised anxiety disorder in situations where pharmacological therapy is appropriate. Escitalopram shows similar efficacy to the other selective serotonin re-uptake inhibitor licensed for the treatment of generalised anxiety disorder.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
08.10.07 *SMC Report No. 406/07*	escitalopram, 5mg, 10mg, and 20mg tablets and 10mg/mL oral drops (Cipralex®) *Lundbeck Ltd* *Treatment of obsessive compulsive disorder.*	NOT RECOMMENDED: escitalopram (Cipralex®) is not recommended for use within NHS Scotland for treatment of obsessive compulsive disorder. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.05.08 *SMC Report No. 475/08* NON SUBMISSION	escitalopram 5, 10 and 20 mg Film-coated tablets and 10 mg/ml oral drops, solution (Cipralex®) *Lundbeck Limited* *Treatment of social anxiety disorder.*	NOT RECOMMENDED: escitalopram (Cipralex) is not recommended for use within NHSScotland for the treatment of social anxiety disorder. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.11.10 *SMC Report No. 592/09* RESUBMISSION Patient Access Scheme	eslicarbazepine acetate 800mg tablets (Zebinix®) *Eisai Ltd.* *Adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation.*	Restricted use: eslicarbazepine acetate (Zebinix®) is accepted for restricted use within NHS Scotland. Indication under review: as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. SMC restriction: patients with highly refractory epilepsy who have been heavily pre-treated and remain uncontrolled with existing anti-epileptic drugs. Eslicarbazepine acetate reduces seizure frequency compared to placebo over a 12-week maintenance period. Direct comparative data versus other anti-epileptic drugs are unavailable, particularly comparisons with other cheaper agents with a very similar mode of action. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eslicarbazepine acetate. This SMC advice is contingent upon the continuing availability of the PAS in Scotland.	Added to the Additional List, Specialist Initiation. FC April 2011
11.10.04 *SMC Report No. 124/04*	esomeprazole intravenous formulation (Nexium IV®) *AstraZeneca* *Treatment of gastroesophageal reflux disease in patients with oesophagitis and/or severe symptoms of reflux as an alternative to oral therapy when oral intake is not appropriate.*	Accepted for use: Intravenous esomeprazole (Nexium IV®) is accepted for use within NHS Scotland for the treatment of gastroesophageal reflux disease in patients with oesophagitis and/or severe symptoms of reflux as an alternative to oral therapy when oral intake is not appropriate. Intravenous esomeprazole seems to be as effective as oral esomeprazole in terms of gastric acid suppression and healing of erosive oesophagitis. However comparisons with other IV proton pump inhibitors are restricted to pre-clinical studies. Esomeprazole has similar acquisition costs to other IV proton pump inhibitors.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
12.06.06 *SMC Report No. 257/06*	esomeprazole 20mg tablets (Nexium®) *AstraZeneca UK Ltd* *Prevention of gastric and duodenal ulcers associated with non-steroidal anti-inflammatory (NSAID) therapy in patients at risk.*	NOT RECOMMENDED: esomeprazole (Nexium®) is not recommended for use within NHS Scotland for the prevention of gastric and duodenal ulcers associated with non-steroidal anti-inflammatory (NSAID) therapy in patients at risk. When compared to placebo, esomeprazole reduces the rate of gastro-duodenal ulcers associated with NSAID therapy in at-risk patients. There are no comparisons of esomeprazole with other proton pump inhibitors for this indication. The economic case has not been demonstrated.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
12.06.06 *SMC Report No. 274/06*	esomeprazole 20mg tablets (Nexium®) *AstraZeneca UK Ltd* *Healing of gastric ulcers associated with non-steroidal anti-inflammatory drug (NSAID) therapy.*	NOT RECOMMENDED: esomeprazole (Nexium®) is not recommended for use within NHS Scotland for the healing of gastric ulcers associated with non-steroidal anti-inflammatory drug (NSAID) therapy. In the treatment of gastric ulcers associated with NSAID therapy, esomeprazole produced greater healing rates than a histamine-H2 antagonist. However, there are no comparisons of esomeprazole with other proton pump inhibitors for this indication. The economic case has not been demonstrated.	NOT RECOMMENDED
11.06.07 *SMC Report No. 368/07*	esomeprazole 20mg and 40mg tablets (Nexium®) *AstraZeneca UK Ltd* *For patients in the age group 12-17 years inclusive, for the treatment of erosive reflux oesophagitis, the long-term management of patients with healed oesophagitis to prevent relapse, and the symptomatic treatment of gastro-oesophageal reflux disease.*	Restricted use: esomeprazole (Nexium®) is accepted for restricted use within NHS Scotland, for patients in the age group 12-17 years inclusive, for the treatment of erosive reflux oesophagitis, the long-term management of patients with healed oesophagitis to prevent relapse, and the symptomatic treatment of gastro-oesophageal reflux disease. The use of esomeprazole for this indication and age group should be restricted to patients in whom maximum licensed doses of generic proton pump inhibitors have been ineffective. The pharmacokinetics of esomeprazole in adolescents have been shown to be similar to those seen in adults; there is no evidence of comparative efficacy in adolescents in this indication.	'Not preferred' in Lothian. FC July 2007
10.12.07 *SMC Report No. 422/07*	esomeprazole, 20mg and 40mg tablets (Nexium®) *AstraZeneca UK Ltd* *Treatment of Zollinger-Ellison Syndrome.*	Accepted for use: esomeprazole (Nexium®) is accepted for use within NHS Scotland for the treatment of Zollinger-Ellison Syndrome. Other proton pump inhibitors are available for this indication at a lower cost per treatment period.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2009
09.11.09 *SMC Report No 578/09*	esomeprazole, 40mg vial of powder for solution for intravenous injection or infusion (Nexium I.V. ®) *AstraZeneca* *Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.*	Accepted for use: esomeprazole (Nexium I.V.®) is accepted for use within NHS Scotland for prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers. In patients with high-risk peptic ulcer bleeding, high-dose intravenous esomeprazole significantly reduced recurrent bleeding at 72 hours compared to placebo.	Added to the LJF as a prescribing note. FC August 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.09.10 *SMC Report No 639/10* PRODUCT UPDATE (abbreviated submission)	esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium®) *AstraZeneca UK Ltd* *Indication listed in next box.*	esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium®): is accepted for restricted use within NHS Scotland. Indication under review: primarily indicated for treatment of gastro-oesophageal reflux disease in children 1 to 11 years old. Gastro-oesophageal reflux disease (GORD) • Treatment of endoscopically proven erosive reflux oesophagitis • Symptomatic treatment of gastro-oesophageal reflux disease Oral suspension may also be used by patients having difficulty swallowing dispersed esomeprazole gastro-resistant tablets. Restricted Advice: the use of esomeprazole for this indication and age group should be restricted to patients in whom licensed doses of a generic proton pump inhibitor have been ineffective. The gastro-resistant granules for oral solution have demonstrated bioequivalence to the tablet and capsule formulations. Doses of 10mg esomeprazole in children aged 1 to 11 resulted in the same exposure to drug as seen with the 20mg dose in adolescents and adults. There is no evidence of comparative efficacy in this population. The Scottish Medicines Consortium has previously accepted this product for use in patients in the 12-17 years age group, for the treatment of erosive reflux oesophagitis, the long-term management of patients with healed oesophagitis to prevent relapse, and the symptomatic treatment of gastro-oesophageal reflux disease.	'Not preferred' in Lothian, as suitable alternatives exist. FC August 2010
09.01.06 *SMC Report No. 227/05*	1mg estradiol and 2mg drospirenone tablets (Angeliq®) *Schering Health Care Ltd* *Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or have contra-indications to, other medicinal products approved for the prevention of osteoporosis.*	NOT RECOMMENDED: 1mg estradiol/2mg drospirenone (Angeliq®) is not recommended for use within NHS Scotland for prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or have contra-indications to, other medicinal products approved for the prevention of osteoporosis. It maintains bone mineral density, relative to placebo, in post-menopausal women. However, no evidence of cost effectiveness has been presented.	NOT RECOMMENDED
09.01.06 *SMC Report No. 230/05*	1mg estradiol and 2mg drospirenone tablets (Angeliq®) *Schering Health Care Ltd* *Hormone replacement therapy for oestrogen deficiency symptoms in postmenopausal women more than 1 year post-menopause.*	NOT RECOMMENDED: 1mg estradiol/2mg drospirenone (Angeliq®) is not recommended for use within NHS Scotland as hormone replacement therapy for oestrogen deficiency symptoms in postmenopausal women more than 1 year post-menopause. It is effective in reducing the frequency of hot flushes and other symptoms of the menopause but comparative data versus other low dose continuous combined treatment are lacking. The cost effectiveness has not been demonstrated and there are cheaper alternatives.	NOT RECOMMENDED
06.12.02 *SMC Report No. 20/02*	estradiol and levonorgestrel transdermal patch (FemSeven Sequi®) *Merck Pharmaceuticals* *Hormone replacement therapy for the treatment of oestrogen deficiency symptoms in postmenopausal women.*	Accepted for use: FemSeven Sequi® is recommended for general use within NHS in Scotland. FemSeven Sequi® offers an alternative sequential combined hormone replacement therapy (HRT) for the treatment of oestrogen deficiency symptoms in postmenopausal women. It is formulated as a transdermal patch and is the first sequential combined HRT patch to allow once weekly application. It is not licensed for the prophylaxis of osteoporosis.	Approved for use - added to the Formulary as second choice drug. FC March 2003

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.01.03 *SMC Report No. 28/02*	estradiol and levonorgestrel transdermal patch (FemSeven Conti®) *Merck Pharmaceuticals* *Continuous combined hormone replacement therapy for the treatment of oestrogen deficiency symptoms in postmenopausal women more than one year after menopause.*	Accepted for use: FemSeven Sequi® is recommended for use within NHS in Scotland. FemSeven Sequi® offers an alternative continuous combined hormone replacement therapy (HRT) for the treatment of oestrogen deficiency symptoms in postmenopausal women more than one year after menopause. It is formulated as a transdermal patch and is the first continuous combined HRT patch to allow once weekly application. It is not licensed for prophylaxis of osteoporosis. HRT patches are in general more expensive than oral preparations.	Approved for use - added to the Additional List. FC March 2003
12.10.09 *SMC Report No. 583/09* NON SUBMISSION	estradiol / dienogest (Qlaira®) *Bayer Schering Pharma* *Oral contraception.*	NOT RECOMMENDED: estradiol/dienogest (Qlaira®) is not recommended for use within NHSScotland for oral contraception. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.07.04 *SMC Report No. 107/04*	etanercept (Enbrel®) *Wyeth Pharmaceuticals* *Treatment of active and progressive psoriatic arthritis in adults.*	Accepted for use: etanercept (Enbrel®) is accepted for use within NHS Scotland for the treatment of active and progressive psoriatic arthritis in adults. It is the first drug to be licensed for this indication and not only improves symptoms of arthritis and psoriasis, but may slow the progression of joint damage (at least over a period of one year).	Added to the LJF, for Specialist Use only. FC August 2004
07.11.05 *SMC Report No. 212/05*	etanercept 25mg vial of powder for subcutaneous injection (Enbrel®) *Wyeth* *New indication: severe active ankylosing spondylitis inadequately controlled by conventional therapy.*	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. It is restricted to use in accordance with the British Society for Rheumatology (BSR) guidelines of July 2004. Etanercept improves signs and symptoms, physical function and quality of life in patients with severe active ankylosing spondylitis. It reduces acute spinal inflammation, but there is no radiological evidence that it decreases joint damage. An economic evaluation, including an assumption that etanercept reduces disease progression, demonstrated that it is a cost effective treatment option when used in accordance with the BSR guidelines and where clear and rigorous stopping rules are applied.	Added to the LJF, for Specialist Use only. FC January 2006
11.09.06 *SMC Report No. 303/06* PRODUCT UPDATE (abbreviated submission)	etanercept 50mg subcutaneous injection (Enbrel®) for ankylosing spondylitis *Wyeth Pharmaceuticals* *New Formulation: treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.*	Restricted use: etanercept 50mg subcutaneous injection (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. It is restricted to use in accordance with the British Society for Rheumatology (BSR) guidelines of July 2004. Etanercept improves signs and symptoms, physical function and quality of life in patients with severe active ankylosing spondylitis. It reduces acute spinal inflammation, but there is no radiological evidence that it decreases joint damage. It is a cost effective treatment option when used in accordance with the BSR guidelines and where clear and rigorous stopping rules are applied. The 50mg formulation facilitates once weekly administration of etanercept at no additional cost over the existing 25mg formulation that is administered twice weekly.	New formulation of a drug already included in the Formulary. FC October 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
11.09.06 *SMC Report No. 305/06* PRODUCT UPDATE (abbreviated submission)	etanercept 50mg subcutaneous injection (Enbrel®) for rheumatoid arthritis *Wyeth Pharmaceuticals* *Treatment of patients with rheumatoid arthritis for whom treatment with etanercept is considered appropriate.*	Accepted for use: etanercept 50mg subcutaneous injection (Enbrel®) is accepted for use within NHS Scotland for the treatment of patients with rheumatoid arthritis for whom treatment with etanercept is considered appropriate. Etanercept is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults, either alone or in combination with methotrexate when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate or for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. The 50mg formulation facilitates once weekly administration of etanercept at no additional cost over the existing 25mg formulation that is administered twice weekly.	New formulation of a drug already included in the Formulary. FC October 2007
07.09.09 *SMC Report No. 570/09* PRODUCT UPDATE (abbreviated submission)	etanercept (Enbrel®) *Wyeth Pharmaceuticals* *Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.*	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. It should be used only when the following criteria are met: -The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10; -The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments; -Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Etanercept has previously been accepted for use in this indication in adults in NHS Scotland as NHS QIS advised that NICE Multiple Technology Appraisal No 103 is valid for Scotland. Etanercept is also listed in the British National Formulary for Children as one of a number of drugs affecting the immune response available for treatment of severe refractory psoriasis.	Added to the Additional List. For Specialist Use only. FC September 2009
14.05.12 *SMC Report No. 781/12* PRODUCT UPDATE (abbreviated submission)	etanercept 10mg and 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®) *Pfizer Ltd* *For the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.*	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. SMC restriction: - The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10; - The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments; - etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Etanercept has previously been accepted for use in this indication in adults in NHS Scotland as NHS Health Improvement Scotland advised that NICE Multiple Technology Appraisal No 103 is valid for Scotland. Etanercept has previously been accepted for restricted use by SMC in adolescents and children from the age of 8 years. Etanercept is also listed in the British National Formulary for Children 2011-2012 as one of a number of drugs affecting the immune response available for treatment of severe refractory psoriasis.	**Included** on the Additional List for the indication in question. Specialist Use only. Added to the Additional List. Specialist Use only. FC May 2012

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
14.05.12 *SMC Report No. 782/12* PRODUCT UPDATE (abbreviated submission)	etanercept 10mg and 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®) *Pfizer Ltd* *For the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.*	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Etanercept has previously been accepted for use for this indication in children and adolescents from the age of 4-17 years in NHS Scotland as NHS Health Improvement Scotland advised that NICE Multiple Technology Appraisal No 35 is valid for Scotland. Etanercept is also listed in the British National Formulary for Children 2011-2012 as one of a number of treatment options for juvenile idiopathic arthritis.	**Included** on the Additional List for the indication in question. Specialist Use only. Added to the Additional List. Specialist Use only. FC May 2012
11.02.13 *SMC Report No. 842/13* PRODUCT UPDATE (abbreviated submission)	etanercept 10mg and 25mg powder and solvent for solution for injection for paediatric use, 25mg and 50mg solution for injection in pre-filled syringe, 50mg solution for injection in pre-filled pen (Enbrel®) *Pfizer Ltd* *For the treatment of* • *polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate;* • *psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate;* • *enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.*	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of: • polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; • psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; • enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy. SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Etanercept has previously been accepted by the SMC for the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Etanercept is listed in the British National Formulary for Children 2011-2012 as one of a number of treatment options for juvenile idiopathic arthritis including the above subtypes.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC January 2013
07.02.03 *SMC Report No. 23/03* RESUBMISSION	ethinylestradiol 30micrograms and drospirenone 3mg (Yasmin®) *Bayer Schering Pharma* *Contraception.*	NOT RECOMMENDED: drospirenone/ethinylestradiol (Yasmin®) is not recommended for use within NHS Scotland. Indication under review: oral contraception. Drospirenone/ethinylestradiol has been shown to have similar contraceptive effectiveness to other combined oral contraceptives in routine use, with no significant differences in adverse event profile. The manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
11.10.10 *SMC Report No. 646/10* PRODUCT UPDATE (abbreviated submission)	ethinylestradiol 30microgram and levonorgestrel 150microgram (Rigevidon® 30/150 microgram) film-coated tablets *Consilient Health Limited* *Oral contraception.*	Accepted for use: ethinylestradiol 30microgram/levonorgestrel 150microgram (Rigevidon®): is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom ethinylestradiol/levonorgestrel is an appropriate contraceptive, Rigevidon® provides an alternative to existing preparations at a lower cost.	Added to the LJF as first choice. FC March 2011
11.10.10 *SMC Report No. 644/10* PRODUCT UPDATE (abbreviated submission)	ethinylestradiol 20 microgram / gestodene 75microgram (Millinette® 20/75microgram) film-coated tablets ethinylestradiol 30 microgram / gestodene 75microgram (Millinette® 30/75microgram) film-coated tablets *Consilient Health Limited* *Oral contraception.*	Accepted for use: ethinylestradiol 20microgram/gestodene 75microgram and ethinylestradiol 30microgram/gestodene 75microgram (Millinette®): is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom ethinylestradiol /gestodene is an appropriate contraceptive, Millinette® provides an alternative to existing preparations at lower cost.	Millinette® 30/75 added to the LJF as second choice. Millinette® 20/75 'Not preferred' in Lothian as suitable alternatives exist. FC March 2011
11.10.10 *SMC Report No. 643/10* PRODUCT UPDATE (abbreviated submission)	ethinylestradiol 20microgram / desogestrel 150microgram (Gedarel® 20/150 microgram) film-coated tablets ethinylestradiol 30microgram / desogestrel 150microgram (Gedarel® 30/150 microgram) film-coated tablets *Consilient Health Limited* *Oral contraception.*	Accepted for use: ethinylestradiol 20microgram/desogestrel 150microgram and ethinylestradiol 30microgram/desogestrel 150microgram (Gedarel®) is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom ethinylestradiol /desogestrel is an appropriate contraceptive, Gedarel® provides an alternative to existing preparations at lower cost.	Gedarel® 30/150 added to the LJF as second choice Gedarel® 20/150 'Not preferred' in Lothian as suitable alternatives exist. FC March 2011
11.10.10 *SMC Report No. 645/10* PRODUCT UPDATE (abbreviated submission)	ethinylestradiol 30/40microgram/levonorgestrel 50/75/125microgram (TriRegol®) *Consilient Health Limited* *Oral contraception.*	Accepted for use: ethinylestradiol 30/40 plus levonorgestrel 50/75/125 microgram (TriRegol®): is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom phasic ethinylestradiol and levonorgestrel is an appropriate contraceptive, TriRegol® provides an alternative to the existing preparation at lower cost.	'Not preferred' in Lothian as suitable alternatives exist. FC March 2011
13.12.04 *SMC Report No. 143/04* PRODUCT UPDATE (abbreviated submission)	etomidate (Etomidate-Lipuro®) *B Braun Medical Ltd* *New formulation of existing combination: Induction of general anaesthesia in patients aged six months and above where etomidate is an appropriate agent.*	Accepted for use: Etomidate-Lipuro® 2mg/ml is accepted for use in NHS Scotland for the induction of general anaesthesia in patients aged six months and above where etomidate is an appropriate agent. Compared with high-osmolality etomidate formulations based on propylene glycol, this formulation may be associated with a reduction in adverse events, including pain on administration and the requirement for a local anaesthetic, at no additional cost.	Added to the Formulary as second choice drug, replacing standard etomidate for general anaesthesia. FC January 2005

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12.10.09 *SMC Report No. 502/08* RESUBMISSION	11.7mg etonogestrel / 2.7mg ethinylestradiol vaginal ring (NuvaRing®) *Schering-Plough* *Contraception.*	Accepted for use: etonogestrel / ethinylestradiol vaginal ring (NuvaRing®) is accepted for use within NHS Scotland for contraception. Results from two randomised phase III clinical studies indicate that the contraceptive efficacy of NuvaRing® is similar to that of two combined oral contraceptives. NuvaRing® produces good cycle control and user acceptability. Cost-effectiveness has been demonstrated in women who chose to discontinue oral contraceptives. Other non-oral contraceptives are available at lower cost.	Added to the Additional List. FC March 2010
13.12.10 *SMC Report No. 655/10* PRODUCT UPDATE (abbreviated submission)	etonogestrel implant 68mg (Nexplanon®) *Merck Sharp & Dohme Limited* *Contraception.*	Accepted for use: etonogestrel implant 68mg (Nexplanon®) is accepted for use within NHS Scotland. Indication under review: contraception. In patients for whom a long-acting etonogestrel implant is an appropriate choice of contraception. This formulation of etonogestrel implant is X-ray opaque, allowing verification of presence and location of implant.	Added to the Formulary. LJF section to be amended to reflect the change in name from Implanon to Nexplanon. FC December 2010
07.03.03 *SMC Report No. 31/03*	etoricoxib (Arcoxia®) *Merck Sharp & Dohme Ltd* *Symptomatic treatment of osteoarthritis and rheumatoid arthritis.*	Accepted for use: etoricoxib is recommended for use within NHS Scotland. Its use should be in accordance with guidance issued by the National Institute for Clinical Excellence (NICE) for COX-2 selective NSAIDs in the treatment of osteoarthritis (OA) and rheumatoid arthritis (RA). Etoricoxib is effective in the symptomatic treatment of OA and RA. It is also effective in the treatment of acute gouty arthritis. It should be used for patients at high risk of gastro-intestinal adverse-effects to non-selective NSAIDs. In common with other COX-2 selective NSAIDs, etoricoxib is associated with less gastrointestinal adverse-effects than non-selective NSAIDs, but the relative risks of cardiovascular events in such patients are unclear. There is no evidence that etoricoxib has advantages or disadvantages compared with other COX-2 selective NSAIDs.	Non-Formulary - 'Not preferred' as effective alternatives available. FC July 2003
09.10.06 SMC Report No. 313/06 PRODUCT UPDATE (abbreviated submission)	etoricoxib 60mg, 90mg and 120mg tablets (Arcoxia®) *Merck Sharpe & Dohme Ltd* *Symptomatic relief of osteoarthritis, rheumatoid arthritis and the pain and signs of inflammation associated with gouty arthritis, in patients for whom the use of etoricoxib is appropriate, taking account of current advice on the place in therapy of specific inhibitors of cyclo-oxygenase-2 (COX-2).*	Accepted for use: etoricoxib 60mg, 90mg and 120mg tablets (Arcoxia®) are accepted for use in NHS Scotland for the symptomatic relief of osteoarthritis, rheumatoid arthritis and the pain and signs of inflammation associated with gouty arthritis, in patients for whom the use of etoricoxib is appropriate, taking account of current advice on the place in therapy of specific inhibitors of cyclo-oxygenase-2 (COX-2). The new tablet formulation is smaller than the existing formulation at the same cost per dose.	'Not preferred' as suitable alternatives exist. FC October 2008
07.09.09 SMC Report No. 576/09 NON SUBMISSION	etoricoxib (Arcoxia®) *Merck Sharpe and Dohme* *Treatment of ankylosing spondylitis.*	NOT RECOMMENDED: etoricoxib (Arcoxia®) is not recommended for use within NHSScotland for the treatment of ankylosing spondylitis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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14.01.13 SMC Report No. 847/12 NON SUBMISSION	etoricoxib (Arcoxia®) 30mg, 60 mg, 90 mg & 120 mg film-coated Tablets *Merck Sharp & Dohme Limited* *Short-term treatment of moderate pain associated with dental surgery.*	NOT RECOMMENDED: etoricoxib (Arcoxia®) is not recommended for use within NHS Scotland for short-term treatment of moderate pain associated with dental surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.08.09 *SMC Report No. 530/09* RESUBMISSION	etravirine 100mg tablet (Intelence®) *Tibotec* *For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients.*	Accepted for use: etravirine (Intelence®), in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is accepted for use within NHS Scotland for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients. In HIV-1 infected adults, with resistance to currently available non-nucleoside reverse transcriptase inhibitors (NNRTIs) and at least three primary protease inhibitor (PI) mutations, who were receiving an optimised background regimen that included boosted darunavir plus nucleoside reverse transcriptase inhibitors (NRTIs) and optional enfuvirtide, etravirine achieved significant improvements in virological, immunological and clinical outcomes when compared with placebo.	Added to the Additional List, for Specialist Use only FC September 2009
09.09.13 *SMC Report No. 901/13* PRODUCT UPDATE (abbreviated submission)	etravirine 25mg, 100mg, 200mg tablets (Intelence®) *Janssen-Cilag* *In combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age.*	Restricted use: etravirine (Intelence®) is accepted for restricted use within NHS Scotland in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age. SMC restriction: to be prescribed under the supervision of specialists in paediatric HIV. SMC has previously accepted etravirine for use in combination with a boosted protease inhibitor and other antiretroviral medicinal products for the treatment of HIV-1 infection in antiretroviral treatment experienced adult patients. Etravirine is listed in the British National Formulary for Children 2012-2013 for the treatment of HIV infection.	**Included** on the Additional List, Specialist Use only for the indication in question. FC August 2013
12.04.10 *SMC Report No. 595/10*	everolimus 5 and 10 mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Limited* *Treatment of patients with advanced renal cell carcinoma (aRCC), whose disease has progressed on or after treatment with VEGF-targeted therapy.*	NOT RECOMMENDED: everolimus (Afinitor®) is not recommended for use within NHS Scotland. Licensed indication under review: the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. Everolimus, in conjunction with best supportive care (BSC), increased median progression-free survival (PFS) by three months compared with placebo plus BSC in heavily pre-treated patients with metastatic renal cell carcinoma. However, the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
09.04.12 *SMC Report No. 787/12* NON SUBMISSION	everolimus (Votubia®) 2.5mg and 5mg tablets *Novartis Pharmaceuticals UK Ltd* *Treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.*	NOT RECOMMENDED: everolimus (Votubia®) is not recommended for use within NHS Scotland for the treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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14.05.12 *SMC Report No. 777/12*	everolimus, 5mg, 10mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Limited* *Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease.*	Accepted for use: everolimus (Afinitor®) is accepted for use within NHS Scotland for the Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease. Everolimus was superior to placebo in prolonging progression-free survival in adults with progressive, advanced pNET who were receiving best supportive care.	**Included** on the Additional List for the indication in question. Specialist Use only. FC July 2012
10.06.13 *SMC Report No. 884/13* NON SUBMISSION	everolimus (Votubia®) 10mg tablets *Novartis Pharmaceuticals Ltd* *Treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.*	NOT RECOMMENDED: everolimus (Votubia®) is not recommended for use within NHS Scotland for the treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.07.13 *SMC Report No. 872/13*	everolimus, 5mg and 10mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Limited* *Treatment of hormone receptor-positive, human epidermal growth factor type 2 (HER2)/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.*	NOT RECOMMENDED: everolimus (Afinitor®) is not recommended for use within NHS Scotland for the treatment of hormone receptor-positive, human epidermal growth factor type 2 (HER2)/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor. The addition of everolimus to exemestane treatment significantly increased progression free survival compared with exemestane alone in postmenopausal women with disease progression following a non-steroidal aromatase inhibitor. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
07.11.05 *SMC Report No. 210/05*	exemestane 25mg tablets (Aromasin®) *Pfizer Limited* *New indication for the adjuvant treatment of postmenopausal women with oestrogen receptor positive invasive early breast cancer, following 2 - 3 years of initial adjuvant tamoxifen therapy*	Restricted use: Exemestane (Aromasin®) is accepted for restricted use within NHS Scotland for the adjuvant treatment of postmenopausal women with oestrogen receptor positive invasive early breast cancer, following 2 - 3 years of initial adjuvant tamoxifen therapy. Exemestane has shown benefit in terms of disease-free survival when given as an alternative to tamoxifen after initial adjuvant treatment with tamoxifen for 2 - 3 years. It offers an alternative to tamoxifen after initial adjuvant treatment with tamoxifen for 2 - 3 years and has a different adverse effects profile. Treatment with exemestane is restricted to initiation by a breast cancer specialist.	Added to the LJF as a prescribing note. FC August 2010
09.07.07 *SMC Report No. 376/07*	exenatide, 5 or 10micrograms, solution for injection, pre-filled pen (Byetta®) *Eli Lilly and Company Limited* *Treatment of type 2 diabetes mellitus in combination with metformin and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.*	Restricted use: exenatide (Byetta®) is accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus in combination with metformin and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. It has shown non-inferiority to two insulin regimens with which it has been compared and has a beneficial effect on weight. It is restricted to use as an alternative to insulin in patients who have failed treatment on metformin and/or sulphonylureas and in whom insulin would be the next treatment option.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. FC November 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.03.11 *SMC Report No. 684/11*	exenatide, 5 or 10 micrograms, solution for injection, pre-filled pen (Byetta®) *Eli Lilly and Company Limited* *Treatment of type 2 diabetes mellitus in combination with thiazolidinediones with or without metformin in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.*	Restricted use: exenatide (Byetta®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of type 2 diabetes mellitus in combination with thiazolidinediones with or without metformin in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. SMC restriction: restricted to use in combination with metformin and a thiazolidinedione as a third-line pre-insulin treatment option. The addition of exenatide to a thiazolidinedione alone or in combination with metformin modestly improved glycaemic control compared with placebo in studies up to 26 weeks, but was associated with nausea and vomiting in some patients. Exenatide has previously been accepted by SMC for restricted use for the treatment of type 2 diabetes mellitus in combination with metformin and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC March 2012
16.01.12 *SMC Report No. 748/11*	exenatide 2mg powder and solvent for prolonged-release suspension for injection (Bydureon®) *Eli Lilly and Company Limited* *For the treatment of type 2 diabetes mellitus in combination with:* *- metformin* *- sulphonylurea* *- thiazolidinedione* *- metformin and sulphonylurea* *- metformin and thiazolidinedione* *in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.*	Restricted use: exenatide once weekly (Bydureon®) is accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus in combination with: - metformin - sulphonylurea - thiazolidinedione - metformin and sulphonylurea - metformin and thiazolidinedione in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. SMC restriction: Exenatide once weekly is restricted to use as a third line treatment option. The economic case for exenatide once weekly for second line use in combination with metformin in place of a sulphonylurea has not been made. In four randomised comparative studies in patients with type II diabetes and receiving oral anti-diabetic agents and/or diet and exercise regimens, exenatide once weekly was superior to the comparators for change in HbA1c. However in a fifth study exenatide once weekly was not superior to another glucagon-like peptide-1 receptor agonist.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. FC November 2013
11.06.12 *SMC Report No. 785/12*	exenatide, 5 micrograms & 10 micrograms, solution for injection, prefilled pen (Byetta®) *Eli Lilly and Company Limited* *As adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults with type 2 diabetes who have not achieved adequate glycaemic control with these agents.*	Accepted for use: exenatide (Byetta®) is accepted for use within NHS Scotland as adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults with type 2 diabetes who have not achieved adequate glycaemic control with these agents. In the pivotal phase lll study, addition of exenatide to basal insulin in combination with other anti-diabetic agents was associated with a clinically significant reduction in HbA1c of -0.7% compared with placebo, with 60% of patients achieving a target HbA1c level ≤7.0%.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC August 2012

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08.03.10 *SMC Report No. 528/09* RESUBMISSION	extended release epidural morphine, 10mg/ml (10mg, 15mg and 20mg) (Depodur®) *Flynn Pharma Ltd* *Relief of post-operative pain following major orthopaedic, abdominal or pelvic surgery.*	NOT RECOMMENDED: extended release epidural morphine (Depodur®) is not recommended for use within NHS Scotland for the relief of post-operative pain following major orthopaedic, abdominal or pelvic surgery. Extended-release epidural morphine has shown some advantages in terms of efficacy versus a single dose of epidural opioid. However, as there are limited comparative data versus epidural analgesia techniques currently used in NHS Scotland it was difficult to assess clinical efficacy in relation to current Scottish practice. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
08.09.03 *SMC Report No. 61/03*	ezetimibe (Ezetrol®) *Merck Sharpe & Dohme / Schering-Plough Ltd (UK)* *Primary hypercholesterolaemia / Homozygous Familial Hypercholesterolaemia / Homozygous sitosterolaemia (phytosterolaemia).*	Restricted use: ezetimibe (Ezetrol®) is recommended for restricted use within NHS Scotland. Ezetimibe may be considered in combination with a statin for patients who have failed to reach target cholesterol levels despite treatment with titrated/optimised statins alone. It may also be considered as monotherapy where statins are inappropriate or poorly tolerated.	Approved for use - added to the Additional List. FC November 2003
13.06.05 *SMC Report No. 182/05* PRODUCT UPDATE (abbreviated submission)	ezetimibe/simvastatin (Inegy®) *Merck Sharp and Dohme/Schering Plough Ltd* *High cholesterol.*	Restricted use: ezetimibe/simvastatin (Inegy®) is accepted for restricted use in NHS Scotland only for patients who have failed to achieve target cholesterol levels after titration and optimisation of statin monotherapy and where the combination of ezetimibe 10mg and simvastatin 20mg, 40mg or 80mg is appropriate. This reflects advice on ezetimibe issued by the Scottish Medicines Consortium in September 2003 (61/03) and is based on the combined tablets being priced at approximately the same level as the individual ingredients.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
09.04.12 *SMC Report No. 789/12* NON SUBMISSION	fampridine 10mg prolonged-release tablets (Fampyra®) *Biogen Idec Ltd* *Improvement of walking in adult patients with multiple sclerosis with walking disability.*	NOT RECOMMENDED: fampridine (Fampyra®) is not recommended for use within NHS Scotland for improvement of walking in adult patients with multiple sclerosis with walking disability. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.09.10 *SMC Report No. 637/10*	febuxostat 80mg and 120mg tablets (Adenuric®) *Menarini Pharma UK SRL* *Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence, of tophus and/or gouty arthritis).*	Restricted use: febuxostat (Adenuric®) is accepted for restricted use within NHS Scotland. Indication under review: Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence, of tophus and/or gouty arthritis). SMC restriction: when treatment with allopurinol is inadequate, not tolerated or contra-indicated. Febuxostat is superior to allopurinol 300mg daily in reducing serum uric acid to <6mg/dL, (360micromol/L) in patients with hyperuricaemia and gout. (NB The maximum licensed daily dose of allopurinol is 900mg.) The economic case was demonstrated for second line use of febuxostat in patients who had an inadequate response to allopurinol, or when allopurinol is contraindicated or not tolerated.	Added to the Formulary as second choice. A prescribing note added for prescribing in relation to allopurinol. FC December 2010

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10.01.03 *SMC Report No. 24/02*	fentanyl transdermal patches (Durogesic®) *Janssen-Cilag Ltd* *Intractable pain due to non malignant conditions.*	Restricted use: fentanyl transdermal patches (Durogesic®) is recommended for restricted use within NHS Scotland. Transdermal fentanyl should be considered as a second-line alternative for patients with intractable pain due to non-malignant conditions. It should be reserved for patients whose pain has initially been controlled by oral means, the pain being relatively stable. Its use should focus on such patients who have difficulty swallowing or have problems with opiate induced constipation. N.B: Transdermal patches are significantly more expensive than oral therapy.	Approved for use - added to the Additional List. Strict protocol to be adopted restricting use for patients whose pain has been stabilised by oral opiates who have difficulty swallowing or have problems with opiate induced constipation. FC May 2003
11.07.05 *SMC Report No. 189/05* PRODUCT UPDATE (abbreviated submission)	fentanyl (Durogesic® D Trans®) transdermal patches *Janssen-Cilag* *Chronic intractable pain due to non-malignant conditions.*	Restricted use: Transdermal fentanyl (Durogesic D Trans®) patch is accepted for restricted use within NHS Scotland for patients with chronic intractable pain due to non-malignant conditions. It should be considered as a second-line alternative, reserved for patients whose pain has initially been controlled by oral means, the pain being stable. Its use should focus on patients who have difficulty swallowing or have problems with opiate-induced constipation. This reiterates advice issued by SMC in January 2003 following the extension of the licence for transdermal fentanyl (Durogesic®) patch to include non-malignant pain. SMC has not assessed transdermal fentanyl in its original indication for intractable pain due to cancer. Note that, although the new formulation is the same price as the previous patches, it remains significantly more expensive than oral therapy.	New formulation of an existing product already approved for use in chronic intractable pain. FC October 2007
08.05.06 *SMC Report No. 250/06* PRODUCT UPDATE (abbreviated submission)	fentanyl (Durogesic D Trans®) transdermal patches 12micrograms/hour *Janssen-Cilag Ltd* *Chronic intractable pain due to non-malignant conditions.*	Restricted use: Transdermal fentanyl (Durogesic D Trans® patches) 12micrograms/hour is accepted for restricted use within NHS Scotland for patients with chronic intractable pain due to non-malignant conditions. It should be considered as a second-line alternative, reserved for patients whose pain has initially been controlled by oral means, the pain being stable. Its use should focus on patients who have difficulty swallowing or have problems with opiate-induced constipation. The new strength allows greater flexibility in dose titration without a substantial impact on price compared with the range of patches previously available. However, it remains significantly more expensive than oral therapy. SMC has not assessed transdermal fentanyl in its original indication for intractable pain due to cancer.	New formulation of an existing product already approved for use in chronic intractable pain. FC October 2007
09.11.09 *SMC Report No: 579/09*	fentanyl 50 micrograms/dose, 100 micrograms/dose, 200 micrograms/dose nasal spray (Instanyl®) *Nycomed UK Ltd.* *Management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.* *Patients receiving maintenance opioid therapy are those who are taking at least 60mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30mg oxycodone daily, at least 8mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.*	Restricted use: fentanyl nasal spray (Instanyl®) is accepted for restricted use within NHS Scotland for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. In an open-label comparative study intranasal fentanyl was superior to another fentanyl formulation used in the treament of breakthrough pain in terms of time to onset of pain relief, although more episodes using the intranasal formulation required a second dose. Use of fentanyl nasal spray should be restricted to patients who are unsuitable for other short-acting oral opioids (e.g. oral morphine) as an alternative to other buccal and sublingual fentanyl preparations. It should be noted that the doses of fentanyl nasal spray are significantly lower than doses of fentanyl given by other routes of administration for this indication.	'Not preferred' in Lothian as suitable alternatives exist. FC December 2009

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
16.01.12 *SMC Report No 750/11* PRODUCT UPDATE *(abbreviated Submission)*	fentanyl 50, 100, 200 microgram single dose nasal spray (Instanyl®) *Nycomed UK Ltd* *For the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.*	Restricted use: fentanyl single dose nasal spray (Instanyl®) is accepted for restricted use in NHS Scotland for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain. Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. SMC restriction: to patients who are unsuitable for other short-acting oral opioids (e.g. oral morphine) as an alternative to other buccal and sublingual fentanyl preparations. It should be noted that the doses of fentanyl nasal spray are significantly lower than doses of fentanyl given by other routes of administration for this indication. In a pharmacokinetic study in healthy volunteers, this single dose fentanyl nasal spray presentation was shown to be bioequivalent to the multi-dose nasal spray presentation and is available at equivalent cost per dose.	'Not preferred' in Lothian as suitable alternatives exist. FC January 2012
09.02.09 *SMC Report No. 510/08*	fentanyl, 100, 200, 400, 600 and 800 microgram buccal tablet (Effentora®) *Cephalon UK Ltd.* *Treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.*	Restricted use: fentanyl buccal tablets (Effentora®) are accepted for restricted use within NHS Scotland for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. When compared with placebo, the tablets showed an improvement in patient assessment of the intensity of breakthrough pain. Use of fentanyl buccal tablets should be restricted to patients who are unsuitable for other short-acting opioids e.g. oral morphine. Prescribers should be aware of the differing absorption and elimination characteristics of available buccal fentanyl preparations; doses are not interchangeable.	'Not preferred' in Lothian as suitable alternatives exist. FC December 2009
09.02.09 *SMC Report No. 534/09* PRODUCT UPDATE *(abbreviated Submission)*	fentanyl 100, 200, 300, 400, 600 and 800 microgram sublingual tablets (Abstral®) *ProStrakan* *Management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain.*	Restricted use: fentanyl sublingual tablets (Abstral®) are accepted for restricted use in NHS Scotland for the management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. Use of sublingual fentanyl tablets should be restricted to patients who are unsuitable for other short-acting opioids e.g. oral morphine. This product offers an alternative to buccal administration at a reduced cost per administration. Prescribers should be aware of the differing absorption and elimination characteristics of available oral fentanyl preparations; doses are not interchangeable.	Added to the Additional List, for Specialist initiation. FC May 2010
17.01.11 *SMC Report No. 663/10*	fentanyl 100microgram/dose and 400microgram/dose nasal spray solution (PecFent®) *Archimedes Pharma* *Management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain.*	Restricted use: fentanyl nasal spray (PecFent®) is accepted for restricted use within NHS Scotland. Indication under review: management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain. SMC restriction: restricted to use in patients unsuitable for short-acting oral opioids, as an alternative to other fentanyl preparations. Fentanyl pectin nasal spray offers an advantage in the time to onset of pain relief and reduction in pain intensity of breakthrough pain compared with placebo and immediate release morphine sulphate. Indirect comparison indicates broadly comparable efficacy to an oral transmucosal fentanyl formulation and an existing fentanyl nasal spray. Prescribers should be aware of the differing absorption and elimination characteristics of the available nasal fentanyl preparations; doses are not interchangeable.	Added to the Additional List, for Specialist initiation. FC August 2011

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13.01.14 *SMC Report No 947/13* NON SUBMISSION	fentanyl citrate (Breakyl®) 200mcg, 400mcg and 800mcg buccal film *Meda Pharmaceuticals* *Treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.*	NOT RECOMMENDED: fentanyl citrate (Breakyl®) is not recommended for use within NHS Scotland for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.02.11 *SMC Report No 691/11* NON SUBMISSION	fenticonazole 2% vaginal cream and 200mg/600mg vaginal capsules (Ginoxin®) *Recordati Pharmaceuticals Limited* *Treatment of vulvovaginal candidiasis.*	NOT RECOMMENDED: fenticonazole (Ginoxin®) is not recommended for use within NHS Scotland. Indication under review: treatment of vulvovaginal candidiasis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.06.11 *SMC Report No 463/08* 2nd RESUBMISSION	ferric carboxymaltose 50mg iron/mL solution for injection/infusion (Ferinject®) *Syner-Med (PP) Ltd* *Treatment of iron deficiency when oral preparations are ineffective or cannot be used.*	Restricted use: ferric carboxymaltose (Ferinject®) is accepted for restricted use within NHS Scotland. Indication under review: the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests. SMC restriction: use is restricted to administration by intravenous infusion within the licensed indication but excluding use in patients receiving haemodialysis. The manufacturer's economic case did not consider the cost-effectiveness of iv bolus administration or use in haemodialysis patients. Ferric carboxymaltose was superior to oral ferrous sulphate in raising haemoglobin levels in non-dialysis-dependent patients with chronic kidney disease and iron deficiency anaemia.	**Included** on the LJF as an equal first choice drug, for Specialist Use only, for the indication in question, for the use in GI and Haematology patients only. FC November 2013
11.02.13 *SMC Report No 833/13*	ferumoxytol, 30mg/mL solution for injection (Rienso®) *Takeda UK Limited* *Intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease.*	Restricted use: ferumoxytol (Rienso®) is accepted for restricted use within NHS Scotland for intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease. SMC restriction: treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used. In two phase III studies the mean increase from baseline in haemoglobin was significantly higher for ferumoxytol than oral iron in non-haemodialysis dependent patients with chronic kidney disease. A mixed treatment comparison demonstrated equivalent efficacy outcomes for ferumoxytol versus a range of intravenous iron preparations.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC March 2013
07.07.08 *SMC Report No 480/08*	fesoterodine fumarate 4mg and 8mg prolonged release tablets (Toviaz®) *Pfizer Ltd* *Treatment of the symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur in patients with overactive bladder syndrome.*	Restricted use: fesoterodine fumarate prolonged release tablets (Toviaz®) is accepted for restricted use within NHS Scotland for treatment of the symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur in patients with overactive bladder syndrome. Fesoterodine is effective in reducing symptoms associated with overactive bladder syndrome without a neurological cause and was of equivalent efficacy to a comparator antimuscarinic agent in one study. Fesoterodine is associated with adverse effects typical of antimuscarinic agents used in this condition. It is restricted to second-line use as there are cheaper antimuscarinics available that would normally be used as first-line agents.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. FC December 2012

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09.07.12 *SMC Report No: 791/12*	fidaxomicin 200mg film-coated tablets (Dificlir®) *Astellas Pharma Ltd* *Treatment of adults with Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD).*	Restricted use: fidaxomicin (Dificlir®) is accepted for restricted use within NHS Scotland for the treatment of adults with Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD). SMC restriction: Treatment of adults with a first CDI recurrence on the advice of local microbiologists or specialists in infectious diseases. Fidaxomicin demonstrated non-inferiority to another antibiotic in the clinical cure of Clostridium difficile infection and superiority in reducing recurrence. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC for first-line use in adults with severe CDI.	**Included** on the LJF, Specialist Use only, for the incidation in question. FC October 2012
09.11.09 *SMC Report No: 577/09*	filgrastim, 30 million units (300 microgram)/0.5mL and 48 million units (480 microgram)/0.8mL, prefilled syringe containing solution for injection or infusion (Ratiograstim®) *Ratiopharm UK Ltd* *Indication listed in next box.*	Accepted for use: filgrastim (Ratiograstim®) is accepted for use within NHS Scotland for: Reduction in the duration of neutropenia and the incidence of febrile neutropenia (FN) in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. Mobilisation of peripheral blood progenitor cells (PBPC). As long term administration, to increase neutrophil counts and to reduce the incidence and duration of infection-related events in children or adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 x 109/L, and a history of severe or recurrent infections. For the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 109/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate. Filgrastim (Ratiograstim®) is a biosimilar product and has demonstrated equivalency in terms of efficacy and safety to a reference granulocyte colony stimulating factor (filgrastim (Neupogen®)). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2011

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09.08.10 *SMC Report No. 629/10* PRODUCT UPDATE (abbreviated submission)	filgrastim, 30 million units (300 microgram)/0.5mL and 48 million units (480 microgram)/0.8mL, prefilled syringe containing solution for injection or infusion (TevaGrastim®) *Teva UK Limited* *Indication listed in next box.*	Accepted for use: filgrastim (TevaGrastim®) is accepted for use within NHS Scotland. Indications under review: • Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); • Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia; • Mobilisation of peripheral blood progenitor cells (PBPC); • In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of < 0.5 x 109/L, and a history of severe or recurrent infections, long term administration is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events; • For the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 109/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate. Filgrastim (TevaGrastim®) is a follow on biosimilar product. It is manufactured at the same production site and is identical to the biosimilar product filgrastim (Ratiograstim®), previously accepted for use by SMC. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	'Not preferred' in Lothian as suitable alternatives exist. FC August 2010
14.01.11 SMC Report No. 671/11	filgrastim 12 million units (120microgram) / 0.2mL, 30 million units (300microgram) / 0.5mL, 48 million units (480microgram) / 0.5mL solution for injection/infusion in pre-filled syringe (Nivestim®) *Hospira UK limited* *Indication listed in next box.*	Accepted for use: filgrastim (Nivestim®) is accepted for use within NHS Scotland. Indications under review: The reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia; The mobilisation of peripheral blood progenitor cells (PBPC); In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of £ 0.5 x 109/l and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events; The treatment of persistent neutropenia (ANC less than or equal to 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate. Filgrastim (Nivestim®) is a biosimilar product and has demonstrated equivalence in terms of efficacy and safety to a reference granulocyte colony stimulating factor, filgrastim (Neupogen®). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	"Not preferred' in Lothian as suitable alternatives exist. FC March 2012

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13.06.11 *SMC Report No. 704/11*	filgrastim, 30 million units (300 micrograms)/0.5mL, 48 million units (480 micrograms)/0.5mL, solution for injection or infusion in pre-filled syringe (Zarzio®) *Sandoz Ltd* *Indication for use detailed over.*	Accepted for use: filgrastim (Zarzio®) is accepted for use within NHS Scotland. Indications under review: • Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. • Mobilisation of peripheral blood progenitor cells (PBPC). • In children and adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 109/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. • Treatment of persistent neutropenia (ANC ≤ 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate. Filgrastim (Zarzio®) is a biosimilar product to a reference granulocyte colony stimulating factor, filgrastim (Neupogen®). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name. Other granulocyte colony stimulating factor products are available at lower cost.	"Not preferred' in Lothian as suitable alternatives exist. FC March 2012

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.09.12 *SMC Report No. 763/12* RESUBMISSION Patient Access Scheme	fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®) *Novartis Pharmaceuticals UK Ltd* *As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS).*	Restricted use: fingolimod (Gilenya®) is accepted for restricted use within NHS Scotland as single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: • Patients with high disease activity despite treatment with a beta-interferon. These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least one relapse in the previous year while on therapy, and have at least nine T2-hyperintense lesions in cranial magnetic resonance imaging (MRI) or at least one gadolinium-enhancing lesion. A "non-responder" could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. or • Patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. SMC restriction: restricted to use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. Fingolimod reduced the annualised relapse rate significantly more than a beta-interferon in patients with clinically active RRMS. An indirect comparison also demonstrated similar efficacy to another disease modifying therapy in established use in RRMS. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fingolimod. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	**Included** on the LJF for the indication in question, Specialist Use only. FC November 2012
08.12.08 *SMC Report No. 521/08* PRODUCT UPDATE (abbreviated submission)	flecainide acetate capsules 200mg (Tambocor XL®) *Meda Pharmaceuticals Ltd* *Treatment of AV nodal reciprocating tachycardia, arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways; paroxysmal atrial fibrillation in patients with disabling symptoms.*	Accepted for use: flecainide capsules (Tambocor XL®) are accepted for use in NHS Scotland for: the treatment of AV nodal reciprocating tachycardia, arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways; paroxysmal atrial fibrillation in patients with disabling symptoms when treatment need has been established and in the absence of left ventricular dysfunction. Arrhythmias of recent onset will respond more readily. The capsules can be used for the maintenance of normal rhythm following conversion by other means. Patients for whom the use of flecainide is appropriate and who are controlled on 200mg daily using the immediate release formulation may be transferred to one 200mg XL capsule with the benefit of once-daily rather than twice-daily dosing at reduced cost.	Added to the Formulary as a 'Prescribing Note'. FC December 2008

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.02.14 *SMC Report No. 864/13* RESUBMISSION Patient Access Scheme	fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) *Alimera Sciences Limited* *Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.*	Restricted use: fluocinolone acetonide intravitreal implant (Iluvien®) is accepted for restricted use within NHS Scotlandfor the treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. SMC restriction: • only in patients in whom the affected eye is pseudophakic (has an artificial lens after cataract surgery) and; • retreatment would take place only if the patient had previously responded to treatment with fluocinolone acetonide and subsequently best corrected visual acuity had deteriorated to less than 20/32. The safety and efficacy of fluocinolone intravitreal implant was assessed in two randomised, double-masked, controlled phase III studies in patients with diabetic macular oedema. Significantly more patients treated with fluocinolone acetonide had a clinically meaningful improvement in visual acuity at two and three years versus sham injection. Subgroup analyses supported this finding in patients with chronic diabetic macular oedema (median duration at least three years) and in patients who were pseudophakic at baseline. Raised intraocular pressure is an important safety issue. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fluocinolone. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC May 2014
10.10.11 *SMC Report No. 728/11*	fluorouracil 0.5% / salicylic acid 10% cutaneous solution (Actikerall®) *Almirall S.A.* *The topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (AK) (grade I/II) in immunocompetent adult patients. Grade I/II intensity is based on the 4-point scale of Olsen et al. (1991).*	Accepted for use: fluorouracil 0.5% / salicylic acid 10% cutaneous solution (Actikerall®) is accepted for use within NHS Scotland. The topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients. Fluorouracil 0.5% / salicylic acid 10% cutaneous solution was superior to another topical treatment for the histological clearance of a specified target actinic keratosis lesion.	**Included** on the LJF as a prescribing note for the indication in question. FC November 2013
13.11.06 *SMC Report No. 176/05*	fludarabine, 10mg tablet and 50mg for injection or infusion (Fludara®) *Schering Health Care Ltd* *Treatment of B-cell chronic lymphocytic leukaemia (CLL) in patients with sufficient bone marrow reserves.*	Restricted use: fludarabine phosphate (Fludara®) is accepted for restricted use within NHS Scotland for the treatment of B-cell chronic lymphocytic leukaemia (CLL) in patients with sufficient bone marrow reserves. First line treatment should only be initiated in patients with advanced disease, Rai stages III/IV (Binet stage C), or Rai stages I/II (Binet stage A/B) where the patient has disease related symptoms or evidence of progressive disease. Fludarabine phosphate has been associated with higher response rates than chlorambucil in clinical trials. No overall survival advantage over other therapies has been demonstrated. Fludarabine is restricted to use by specialists in haemato-oncology.	Added to the Additional List, for Specialist Use only. FC July 2009

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
14.04.09 *SMC Report No. 544/09*	fluticasone furoate, 27.5 micrograms /actuation nasal spray (Avamys®) *GlaxoSmithKline* *Treatment of the symptoms of allergic rhinitis in adults, adolescents (12 years and over) and children (6 to 11 years).*	Accepted for use: fluticasone furoate (Avamys®) is accepted for use within NHS Scotland for the treatment of the symptoms of allergic rhinitis in adults, adolescents (12 years and over) and children (6 to 11 years). Evidence to support its efficacy comes from a number of comparator- and placebo-controlled studies conducted in adults and children with seasonal and perennial allergic rhinitis. Prescribers should be aware that the recommended doses of fluticasone furoate are not equivalent, on a microgram per microgram basis, to other fluticasone nasal sprays currently available. Other intranasal steroids are available at a lower cost.	Added to the Additional List. FC July 2009
07.04.14 *SMC Report No. 953/14*	fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar Ellipta®) *GlaxoSmithKline UK* *Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV_1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.*	Restricted use: fluticasone furoate/vilanterol (Relvar Ellipta®) is accepted for restricted use within NHS Scotland for symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. SMC restriction: in patients with severe COPD (FEV1 <50% predicted normal). In a comparative, 12-week study there was no statistically significant difference between fluticasone furoate/vilanterol 92/22 micrograms and another inhaled corticosteroid/long acting beta agonist combination inhaler for change from baseline trough in 24-hour weighted-mean FEV1. Fluticasone furoate/vilanterol is also licensed for the treatment of asthma. SMC is due to issue advice for this indication in June 2014.	**Not included** on the LJF, pending protocol. FC May 2014
09.06.14 *SMC Report No. 966/14*	fluticasone furoate / vilanterol 92/22, 184/22 micrograms inhalation powder (Relvar Ellipta®) *GlaxoSmithKline UK* *The regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting $beta_2$-agonist and inhaled corticosteroid) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting $beta_2$-agonists.*	Accepted for use: fluticasone furoate / vilanterol (Relvar Ellipta®) is accepted for use within NHS Scotland as the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting $beta_2$-agonist and inhaled corticosteroid) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting $beta_2$-agonists. There was no statistically significant difference between fluticasone furoate/vilanterol 92/22 micrograms daily and another inhaled corticosteroid/long acting $beta_2$-agonist combination (ICS/LABA) inhaler for 0 to 24 hour serial weighted mean forced expiratory volume in one second, at 24 weeks. Some alternative ICS/LABA combination inhalers are available at a lower daily cost.	**Not included** on the LJF, pending protocol. FC July 2014

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
08.10.12 *SMC Report No. 736/11* PRODUCT UPDATE (abbreviated submission)	fluticasone proprionate and formoterol fumarate metered dose inhaler, 50microgram/5microgram, 125microgram/5 microgram 250microgram/10 microgram (flutiform®) *Napp Pharmaceuticals Ltd* *In the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β_2 agonist (LABA)] is appropriate:* *- for patients not adequately controlled on ICS and 'as required' inhaled short-acting β_2 agonist or* *- for patients already adequately controlled on both an ICS and a LABA.*	Accepted for use: fluticasone proprionate and formoterol fumarate metered dose inhaler (flutiform®) is accepted for use in NHS Scotland in the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β_2 agonist (LABA)] is appropriate: • for patients not adequately controlled on ICS and 'as required' inhaled short-acting β_2 agonist or • for patients already adequately controlled on both an ICS and a LABA. Flutiform® should be used in patients for whom fluticasone and formoterol are appropriate choices of corticosteroid and long-acting beta-agonist, respectively, and for whom a metered dose inhaler is an appropriate delivery device. It has demonstrated clinical non-inferiority to another combination product containing a corticosteroid and long-acting beta$_2$-agonist and may offer cost savings.	**Included** on the Additional List for the indication in question, suitable for prescribing where fluticasone, formoterol and a MDI are suitable. FC October 2012
08.12.03 *SMC Report No. 82/03*	fluticasone, salmeterol (Seretide Accuhaler®) *GlaxoSmithKline* *Severe chronic obstructive pulmonary disease.*	Accepted for use: fluticasone/salmeterol (Seretide Accuhaler®) is accepted for use within NHS Scotland for the treatment of patients with severe chronic obstructive pulmonary disease. It is the first of two long-acting β_2-agonist/corticosteroid combination inhaler preparations considered by SMC and licensed for the symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD). The individual components have been available for many years and the combination product offers ease of administration and additional convenience. The combination appears to improve lung function to a greater extent than either of the individual constituents given alone. Comparative data with other combination products are limited at the present time.	Added to the Formulary. Combination inhaler for the treatment of severe COPD. FC April 2004
09.02.04 *SMC Report No. 76/04*	fluvastatin (Lescol®/Lescol XL®) *Novartis Pharmaceuticals* *Secondary prevention of coronary events after percutaneous coronary angioplasty (PCI).*	Restricted use: fluvastatin is accepted for restricted use within NHS Scotland for the secondary prevention of coronary events after percutaneous coronary angioplasty (PCI). Fluvastatin is best placed for the management of patients previously untreated with a statin. In Scotland a significant number of patients being considered for coronary angioplasty are likely to have been prescribed a statin for secondary prevention indications prior to referral for PCI, and in these patients there is no need to change the statin used. Fluvastatin was found to reduce the risk of a major adverse coronary event in patients post-PCI. The reduction in risk was greatest in patients with diabetes mellitus and multivessel disease. The economic model compared fluvastatin to placebo rather than active treatment and, for this comparison, it was cost effective.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
08.11.02 *SMC Report No. 18/02*	fondaparinux (Arixtra®) *Sanofi-Synthelabo* *Prevention of venous thromboembolism (post-op).*	Accepted for use: fondaparinux (Arixtra®) is appropriate for use in NHS Scotland. Compared with enoxaparin, fondaparinux has been shown to be associated with fewer thrombo-embolic events and a generally similar incidence of major bleeding. It is licensed for post-operative initiation, and this represents an advantage where regional anaesthesia and/or catheterisation are planned. It is predicted to be a cost effective alternative to enoxaparin in a robust economic model. It may be considered for patients for whom antithrombotic therapy is appropriate, recognising that other antithrombotic agents and other approaches to prophylaxis may be more suitable in some situations.	Approved for use - added to the LJF. For use in orthopaedic units as thromboprophylaxis in potential hip fractures and hip and knee replacement surgery. Specialist Use only. FC April 2004

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.05.06 *SMC Report No. 261/06* NON SUBMISSION	fondaparinux (Arixtra®) *GlaxoSmithKline* *Prevention of venous thromboembolic events (VTE).*	NOT RECOMMENDED: fondaparinux (Arixtra®) is not recommended for use within NHSScotland for the prevention of venous thromboembolic events (VTE) in medical patients who are judged to be at high risk of VTE and who are immobilised due to acute illness, such as cardiac insufficiency and/or acute respiratory disorders, and/or acute infections or inflammatory disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.05.06 *SMC Report No. 262/06* NON SUBMISSION	fondaparinux (Arixtra®) *GlaxoSmithKline* *Treatment of acute deep vein thromboembolic events (DVT) and the treatment of acute pulmonary embolism (PE).*	NOT RECOMMENDED: fondaparinux (Arixtra®) is not recommended for use within NHSScotland for the treatment of acute deep vein thrombosis (DVT) and the treatment of acute pulmonary embolism (PE). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.08.06 *SMC Report No. 287/06*	fondaparinux 2.5mg/0.5mL solution for injection (Arixtra®) *GlaxoSmithKline* *Prevention of venous thromboembolic events (VTE) in patients undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as those undergoing abdominal cancer surgery.*	NOT RECOMMENDED: fondaparinux (Arixtra®) is not recommended for use within NHS Scotland for the prevention of venous thromboembolic events (VTE) in patients undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as those undergoing abdominal cancer surgery. Fondaparinux showed non-inferiority to one other low molecular weight heparin in preventing VTE in patients undergoing abdominal surgery. The economic case has not been demonstrated.	NOT RECOMMENDED
10.12.07 *SMC Report No. 420/07*	fondaparinux sodium, 2.5mg/0.5ml solution for injection, pre-filled syringe (Arixtra®) *GlaxoSmithKline* *Treatment of unstable angina or non-ST segment elevation myocardial infarction in patients for whom urgent (<120minutes) invasive management (Percutaneous Coronary Intervention) is not indicated.*	Accepted for use: fondaparinux (Arixtra®) is accepted for use within NHS Scotland for the treatment of unstable angina or non-ST segment elevation myocardial infarction in patients for whom urgent (<120minutes) invasive management (Percutaneous Coronary Intervention) is not indicated. Fondaparinux was shown to be non-inferior to a low molecular weight heparin in preventing death, myocardial infarction or refractory ischaemia in the nine days following onset of symptoms. Fondaparinux also had a significantly lower major bleeding event rate than a low molecular weight heparin.	Added to the LJF replacing enoxaparin as first choice in unstable angina, non-ST segment elevation MI and ST segment elevation MI. FC March 2008
11.02.08 *SMC Report No. 439/08*	fondaparinux sodium 2.5mg/0.5ml pre-filled syringe for injection (Arixtra®) *GlaxoSmithKline* *Treatment of ST segment elevation myocardial infarction (STEMI) in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy.*	Accepted for use: fondaparinux sodium (Arixtra®) is accepted for use within NHS Scotland for the treatment of ST segment elevation myocardial infarction (STEMI) in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy. Fondaparinux significantly reduced mortality and reinfarction during the 30 days following onset of symptoms compared to placebo and was not associated with an increased risk of bleeding.	Added to the LJF replacing enoxaparin as first choice in unstable angina, non-ST segment elevation MI and ST segment elevation MI. FC March 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.12.10 *SMC Report No. 668/10* NON SUBMISSION	fondaparinux sodium 1.5mg/0.3mL solution for injection, pre-filled syringe (Arixtra®) *GlaxoSmithKline* *Treatment of acute symptomatic spontaneous superficial-vein thrombosis of the lower limbs without concomitant deep-vein thrombosis.*	NOT RECOMMENDED: fondaparinux sodium (Arixtra®) is not recommended for use within NHS Scotland. Indication under review: treatment of acute symptomatic spontaneous superficial-vein thrombosis of the lower limbs without concomitant deep-vein thrombosis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED:
13.02.06 *SMC Report No. 239/06* PRODUCT UPDATE (abbreviated submission)	formoterol 12micrograms metered dose inhaler (Atimos® Modulite®) *Trinity Chiesi Pharmaceuticals* *Long-term symptomatic treatment of persistent, moderate to severe asthma in patients requiring regular bronchodilator therapy in combination with long-term anti-inflammatory therapy (inhaled and/or oral glucocorticoids).*	Accepted for use: formoterol 12micrograms metered inhaler (Atimos® Modulite®) is accepted for use in NHS Scotland for the long-term symptomatic treatment of persistent, moderate to severe asthma in patients requiring regular bronchodilator therapy in combination with long-term anti-inflammatory therapy (inhaled and/or oral glucocorticoids). It should be used in patients for whom formoterol is an appropriate choice of long-acting beta-agonist and for whom a metered dose inhaler is an appropriate delivery device.	New formulation of a drug already included in the Formulary. FC December 2008
08.10.07 SMC Report No. 349/07 PRODUCT UPDATE (abbreviated submission)	formoterol 12micrograms metered dose inhaler (Atimos® Modulite®) *Trinity-Chiesi Ltd* *Relief of broncho-obstructive symptoms in patients with chronic obstructive pulmonary disease (COPD).*	Accepted for use: formoterol 12micrograms metered dose inhaler (Atimos® Modulite®) is accepted for use in NHS Scotland for the relief of broncho-obstructive symptoms in patients with chronic obstructive pulmonary disease (COPD). It should be used in patients for whom formoterol is an appropriate choice of long-acting beta-agonist and for whom a metered dose inhaler is an appropriate delivery device.	New formulation of a drug already included in the Formulary. FC December 2008
11.06.07 *SMC Report No. 375/07* PRODUCT UPDATE (abbreviated submission)	formoterol 12micrograms metered dose inhaler (Easyhaler®) *Ranbaxy (UK) Ltd* *Treatment of asthma in patients treated with inhaled corticosteroids and who also require a long-acting beta$_2$-agonist in accordance with current treatment guidelines; and for the relief of reversible airways obstruction in patients with chronic obstructive pulmonary disease (COPD) and requiring long-term bronchodilator therapy.*	Accepted for use: formoterol inhalation powder (Easyhaler® Formoterol) is accepted for use within NHS Scotland for the treatment of asthma in patients treated with inhaled corticosteroids and who also require a long-acting beta$_2$-agonist in accordance with current treatment guidelines; and for the relief of reversible airways obstruction in patients with chronic obstructive pulmonary disease (COPD) and requiring long-term bronchodilator therapy. It should be used in patients for whom formoterol is an appropriate choice of long-acting beta$_2$-agonist and a dry powder inhaler is an appropriate delivery device. It costs less than other inhalers delivering similar doses of formoterol.	New formulation of a drug already included in the Formulary. FC October 2007
11.07.05 *SMC Report No. 188/05*	fosamprenavir 700mg tablets and oral suspension 50mg/ml (Telzir®) *GlaxoSmithKline UK* *Treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults in combination with other antiretroviral medicinal products.*	Accepted for use: fosamprenavir (Telzir®) in combination with low dose ritonavir is accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults in combination with other antiretroviral medicinal products. It should be prescribed by HIV specialists only.	Added to the Additional List, for Specialist Use only. FC October 2005

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.09.09 *SMC Report No. 431/07* PRODUCT UPDATE (abbreviated submission)	fosamprenavir 50mg/ml oral suspension and 700mg film-coated tablet (Telzir®) *GlaxoSmithKline UK Ltd* *Treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adolescents and children of six years and above in combination with other antiretroviral medicinal products.*	Accepted for use: fosamprenavir (Telzir®) in combination with low dose ritonavir is accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adolescents and children of six years and above in combination with other antiretroviral medicinal products. Fosamprenavir is listed in the British National Formulary for Children for the treatment of HIV infection. The Scottish Medicines Consortium has previously accepted this product for use in this indication in adults.	Added to the Additional List, for Specialist Use only. FC September 2009
13.10.08 *SMC Report No. 506/08*	fosaprepitant, 115mg powder for solution for infusion (Ivemend®) *Merck Sharp & Dohme Limited* *The prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.*	Restricted use: fosaprepitant (Ivemend®) is accepted for restricted use within NHS Scotland for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. Fosaprepitant is marginally more expensive than aprepitant. It is restricted to use in patients for whom aprepitant is indicated but the oral formulation is not appropriate. Prescribing should be initiated by hospital based specialists only. Fosaprepitant is also licensed for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. As the manufacturer's submission related only to its use with highly emetogenic cancer chemotherapy, SMC cannot recommend its use in this setting.	Added to the Additional List, for Specialist Use only. FC July 2009 PRODUCT WITHDRAWN FROM THE UK MARKET – 15 FEBRUARY 2011
07.03.11 *SMC Report No. 678/11* PRODUCT UPDATE (abbreviated submission)	fosaprepitant dimeglumine 150 mg powder for solution for infusion (IVEmend®) *MSD Ltd* *Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults.* *IVEmend 150 mg is given as part of a combination therapy.*	Accepted for use: fosaprepitant dimeglumine (IVEmend 150mg®) is accepted for use within NHS Scotland. Indication under review: Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults. IVEmend 150 mg is given as part of a combination therapy. Fosaprepitant 150mg is not recommended for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults, as SMC has previously not recommended both fosaprepitant iv and aprepitant capsules for this indication.	Added to the Additional List, for Specialist Use only. FC March 2011
09.02.04 *SMC Report No. 49/03* RESUBMISSION	frovatriptan (Migard®) *A Menarini UK* *Treatment of the headache phase of migraine attacks with or without aura.*	Accepted for use: frovatriptan (Migard®) is accepted for use within NHS Scotland for treatment of the headache phase of migraine attacks with or without aura. It is the seventh 5-HT_1 agonist to be marketed in the UK for this indication. It is less effective at rapidly relieving migraine when compared with the most commonly prescribed drug in this class, but has a similar duration of effect. It is also less expensive than other 5-HT_1 agonists.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
09.08.04 *SMC Report No. 114/04*	fulvestrant (Faslodex®) *AstraZeneca UK* *Treatment of postmenopausal women with advanced breast cancer who relapse or progress following prior anti-oestrogen therapy.*	NOT RECOMMENDED: fulvestrant is not recommended for use within NHS Scotland for the treatment of postmenopausal women with advanced breast cancer who relapse or progress following prior anti-oestrogen therapy. Fulvestrant is no more effective than aromatase inhibitors when used following the failure of tamoxifen, and it is approximately four times more expensive. There are no clinical data on the use of fulvestrant following failure of aromatase inhibitors. The licence holder has indicated their decision to resubmit.	NOT RECOMMENDED

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13.06.05 *SMC Report No. 139/04* PRODUCT UPDATE (abbreviated submission)	galantamine hydrobromide (Reminyl XL®) *Shire Pharmaceuticals* *New formulation of existing therapy: Treatment of mild-to-moderately severe dementia in Alzheimer's disease in patients for whom therapy with galantamine is appropriate.*	Accepted for use: galantamine hydrobromide as Reminyl XL® prolonged-release capsules is accepted for use in NHS Scotland for the treatment of mild-to-moderately severe dementia in Alzheimer's disease in patients for whom therapy with galantamine is appropriate. It allows the reduction of dosing frequency to once daily and, at a given dose, involves no additional cost compared with immediate-release formulations of galantamine.	Added to the Formulary for initiation by Specialist only (new formulation of existing therapy). The shared care protocol for galantamine will be updated with these changes. FC April 2006
13.12.10 *SMC Report No: 615/10* RESUBMISSION	gefitinib 250mg film-coated tablets (Iressa®) *AstraZeneca UK Ltd* *Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).*	NOT RECOMMENDED: gefitinib (Iressa®) is not recommended for use within NHS Scotland. Indication under review: the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK). In a comparative study in previously untreated patients, gefitinib was superior to a platinum-based doublet chemotherapy regimen in terms of progression-free survival; subgroup analysis supported this finding in patients with activating mutations of EGFR-TK. However, the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and the economic case was not sufficiently robust to gain acceptance by SMC.	NOT RECOMMENDED
11.12.06 *SMC Report No. 154/05* RESUBMISSION	gemcitabine 200mg and 1g powder for solution for infusion (Gemzar®) *Eli Lilly and Company Ltd* *In combination with paclitaxel, for the treatment of patients with metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy.*	Restricted use: gemcitabine (Gemzar®), in combination with paclitaxel, is accepted for restricted use within NHS Scotland for the treatment of patients with metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated. Gemcitabine in combination with paclitaxel modestly improves outcomes, compared to paclitaxel monotherapy, in those previously treated with an anthracycline. For this indication gemcitabine is restricted to use by oncologists specialising in the treatment of breast cancer.	Added to the Additional List, for Specialist Use only. FC December 2007
09.06.08 *SMC Report No. 471/08*	glucosamine (as hydrochloride), 625mg tablets (Alateris®) *William Ransom & Son plc* *Relief of symptoms in mild to moderate osteoarthritis of the knee.*	NOT RECOMMENDED: glucosamine (as hydrochloride) (Alateris®) is not recommended for use within NHS Scotland for relief of symptoms in mild to moderate osteoarthritis of the knee. No direct clinical trial evidence of the efficacy and safety of this specific product is available. Randomised controlled trials of other formulations of glucosamine hydrochloride indicate little or no benefit over placebo in improving symptoms in patients with osteoarthritis of the knee. In addition, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
08.08.11 *SMC Report No. 647/10* RESUBMISSION	glucosamine sulphate, 1,500mg powder for oral solution (Glusartel®) *Rottapharm Madaus* *Relief of symptoms in mild to moderate osteoarthritis (OA) of the knee.*	NOT RECOMMENDED: glucosamine sulphate (Glusartel®) is not recommended for use within NHS Scotland. Indication under review: relief of symptoms in mild to moderate osteoarthritis of the knee. In a placebo- and active-comparator study, glucosamine sulphate 1,500mg once daily was significantly better than placebo in the treatment of symptoms associated with osteoarthritis of the knee. Overall the submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
08.08.11 *SMC Report No: 729/11* NON SUBMISSION	glucosamine sulphate (Dolenio®) *Blue Bio Pharmaceuticals Ltd* *Symptomatic treatment of mild to moderate osteoarthritis (OA) of the knee.*	NOT RECOMMENDED: glucosamine sulphate (Dolenio®) is not recommended for use within NHS Scotland. Indication under review: symptomatic treatment of mild to moderate osteoarthritis (OA) of the knee. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.02.08 *SMC Report No. 200/05* THIRD RESUBMISSION	glyceryl trinitrate 0.4% rectal ointment (Rectogesic®) *ProStrakan* *Relief of pain associated with chronic anal fissure.*	NOT RECOMMENDED: glyceryl trinitrate 0.4% ointment (Rectogesic®) is not recommended for use within NHS Scotland for relief of pain associated with chronic anal fissure. It was associated with very small improvements in pain scores compared with vehicle, and therefore little clinically significant effect. The manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED
14.01.13 *SMC Report No. 829/12*	glycopyrronium 44 micrograms hard capsules of inhalation powder (Seebri Breezhaler®) *Novartis Pharmaceuticals Ltd.* *As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).*	Accepted for use: glycopyrronium inhalation powder (Seebri Breezhaler®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). In two phase III studies, glycopyrronium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [FEV_1]) after 12 weeks.	**Included** on the LJF as a joint second line treatment, for the indication in question. FC March 2013
09.07.12 *SMC Report No. 674/11* RESUBMISSION	golimumab, 50mg, solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (Simponi®) *Merck, Sharp & Dohme* *Alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.*	Restricted use: golimumab (Simponi®) is accepted for restricted use within NHS Scotland. Indication under review: Alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. SMC restriction: golimumab is restricted to use in patients whose disease has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is also restricted to use at a dose of 50mg only. Golimumab has demonstrated efficacy when compared with placebo in patients with active psoriatic arthritis who have had an inadequate response to DMARDs or non-steroidal anti-inflammatory drugs (NSAIDs). The economic case was demonstrated for golimumab when used at a dose of 50mg. The economic case was not demonstrated for the 100mg dose of golimumab.	**Not included** on the LJF because clinicians do not support the formulary inclusion. FC August 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.09.11 *SMC Report No. 721/11*	golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®) *MSD* *Treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.*	Restricted use: golimumab (Simponi®) is accepted for restricted use within NHS Scotland treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy. SMC restriction: golimumab is restricted to use in accordance with the British Society for Rheumatology (BSR) guidelines for anti-TNFα agents in adults with ankylosing spondylitis. Golimumab is restricted to use at a dose of 50mg only. In a placebo controlled study golimumab 50mg and 100mg were superior to placebo given every four weeks in terms of the proportion of patients who achieved at least 20% improvement in the Assessment in AS International Working group Criteria at week 14. An indirect comparison indicates that golimumab has similar efficacy to two other anti-TNFα agents used in the treatment of ankylosing spondylitis. The economic case was demonstrated for golimumab when used at a dose of 50mg. The economic case was not demonstrated for the 100mg dose of golimumab.	Added to the Additional List, Specialist Use only FC January 2012
07.11.11 *SMC Report No. 733/11*	golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®) *MSD Ltd* *In combination with methotrexate, for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drug therapy including methotrexate has been inadequate.*	Restricted use: golimumab (Simponi®) is accepted for restricted use within NHS Scotland in combination with methotrexate, for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drug therapy including methotrexate has been inadequate. Golimumab, in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. SMC restriction: golimumab is restricted for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005). Golimumab is restricted to use at a dose of 50 mg only. There are no head to head studies comparing golimumab with other TNFα inhibitors in the treatment of rheumatoid arthritis. Golimumab plus methotrexate was superior to methotrexate alone for the primary endpoint (ACR20 response and improvement in HAQ-DI) in patients with active rheumatoid arthritis despite methotrexate treatment. The economic case was demonstrated for golimumab when used at a dose of 50 mg. The economic case was not demonstrated for the 100 mg dose of golimumab. Golimumab is also licensed for use in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. SMC cannot recommend the use of golimumab in this setting, however, as the company submission related only to its use in patients with an inadequate response to methotrexate.	**Not included** on the LJF because clinicians do not support the formulary inclusion. 'Not Preferred' as suitable alternatives exist. FC May 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.01.14 *SMC Report No: 946/13* NON SUBMISSION	golimumab (Simponi®) 50 mg and 100mg solution for injection *Merck Sharpe & Dohme Limited* *Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.*	NOT RECOMMENDED: golimumab (Simponi®) is not recommended for use within NHS Scotland for the reatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.10.13 *SMC Report No. 895/13* PRODUCT UPDATE (abbreviated submission)	granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) *ProStrakan Ltd* *In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult.*	Accepted for use: granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) is accepted for use within NHS Scotland in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult. Granisetron 3.1mg / 24 hours transdermal patch is slightly more expensive than the oral formulation. It provides an alternative option in patients who have difficulty swallowing oral medication.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC October 2013
17.01.11 *SMC Report No. 666/10*	histamine dihydrochloride, 500 microgram/0.5ml, vial (Ceplene®) *Meda Pharmaceuticals Ltd* *Maintenance therapy for adult patients with acute myeloid leukaemia in first remission concomitantly treated with interleukin-2. The efficacy of histamine dihydrochloride has not been fully demonstrated in patients older than age 60 years.*	NOT RECOMMENDED: histamine dihydrochloride (Ceplene®) is not recommended for use within NHS Scotland. Indication under review: maintenance therapy for adult patients with acute myeloid leukaemia in first remission concomitantly treated with interleukin-2. The efficacy of histamine dihydrochloride has not been fully demonstrated in patients older than age 60 years. In a randomised open-label study, histamine plus interleukin-2 was superior to no treatment for the endpoint of leukaemia free survival (LFS) in a sub-group of patients in first complete remission. In post hoc analysis of patients in first complete remission and aged less than 60 years, LFS rates at 36 months were 50% versus 30%. Overall the manufacturer did not present a sufficiently robust clinical or economic case to gain acceptance by SMC.	NOT RECOMMENDED
10.08.09 *SMC Report No. 557/09*	histrelin acetate, 50mg subcutaneous implant (Vantas®) *Orion Pharma (UK) Ltd* *Palliative treatment of advanced prostate cancer.*	Restricted use: histrelin (Vantas®) subcutaneous implant is accepted for restricted use within NHS Scotland for palliative treatment of advanced prostate cancer. Histrelin is restricted to use in patients with an anticipated life expectancy of at least one year in whom annual administration will offer advantages. In a single-arm study, histrelin provided effective suppression of testosterone levels in patients with advanced prostate cancer. It requires less frequent administration than other leutenising hormone releasing hormone (LHRH) agonists. Other LHRH agonists are available at a lower acquisition cost.	'Not preferred' in Lothian as suitable alternatives exist. FC January 2010
14.01.13 *SMC Report No. 848/12* NON SUBMISSION	hydrocortisone (Plenadren®) 5mg and 20mg tablets ViroPharma Limited *Treatment of adrenal insufficiency in adults.*	NOT RECOMMENDED: hydrocortisone (Plenadren®) is not recommended for use within NHS Scotland for the treatment of adrenal insufficiency in adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
12.10.09 *SMC Report No. 582/09* NON SUBMISSION	hydroxycarbamide (Siklos®) *Nordic Pharma UK* *Prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in paediatric and adult patients suffering from symptomatic Sickle Cell Syndrome.*	NOT RECOMMENDED: hydroxycarbamide (Siklos®) is not recommended for use within NHSScotland for the prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in paediatric and adult patients suffering from symptomatic Sickle Cell Syndrome. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland	NOT RECOMMENDED
11.10.04 *SMC Report No. 122/04*	ibandronic acid (Bondronat®) HCM *Roche* *Hypercalcaemia of malignancy.*	Accepted for use: ibandronic acid is accepted for use within NHS Scotland for the treatment of tumour-induced hypercalcaemia with or without metastases. It has been shown to be a cost effective option in reducing serum calcium in patients with hypercalcaemia of malignancy.	Added to the Formulary. FC February 2005
11.10.04 *SMC Report No. 123/04*	ibandronic acid (Bondronat®) *Roche* *Prevention of skeletal events in patients with breast cancer and metastatic bone disease.*	Accepted for use: ibandronic acid is accepted for use within NHS Scotland for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. It reduces the rate of skeletal events consisting of a composite of vertebral fractures, pathological non-vertebral fractures and the need for radiotherapy or surgery to deal with bone complications. It can be given both by the oral or intravenous route.	Added to the Formulary as first choice bisphosphonate, on the advice of an oncologist/ haematologist, for the prevention of skeletal related events in patients with breast cancer. FC February 2005
13.02.06 *SMC Report No. 228/05*	ibandronic acid (also known as ibandronate), 150mg, film-coated tablet (Bonviva®) *Roche/GSK* *Treatment of osteoporosis in postmenopausal women in order to reduce the risk of vertebral fractures.*	Accepted for use: ibandronic acid (Bonviva®) is accepted for use within NHS Scotland for the treatment of osteoporosis in postmenopausal women in order to reduce the risk of vertebral fractures. Ibandronic acid 150mg monthly is superior to daily ibandronic acid in terms of lumbar spine bone mineral density at 1 year. Compared with placebo, daily administration of ibandronic acid results in a relative risk reduction for vertebral fractures of 62%. Unlike some other bisphosphonates, efficacy in reducing femoral neck fractures (and other non-vertebral fractures) has not been established.	Added to the LJF as a prescribing note, for use in patients intolerant of other bisphosphonates and strontium ranelate. FC January 2007
11.09.06 *SMC Report No. 301/06*	ibandronic acid (also known as ibandronate), 3mg in 3ml solution for injection in pre-filled syringe (Bonviva®) *Roche/GlaxoSmithKline* *Treatment of osteoporosis in postmenopausal women, in order to reduce the risk of vertebral fractures.*	Restricted use: Intravenous ibandronic acid (Bonviva®) is accepted for restricted use within NHS Scotland for the treatment of osteoporosis in postmenopausal women, in order to reduce the risk of vertebral fractures. Efficacy on femoral neck fractures has not been established. Intravenous ibandronic acid is restricted to use in patients who are unsuitable for or unable to tolerate oral treatment options for osteoporosis. Treatment initiation should be under specialist supervision.	Added to the Formulary as a prescribing note- Specialist Use only. FC June 2008.
09.07.07 *SMC Report No. 171/05* RESUBMISSION	ibritumomab tiuxetan (Zevalin®) *Schering Health Care Ltd* *For the preparation of a radiopharmaceutical incorporating Yttrium 90 [^{90}Y] for the treatment of adult patients with rituximab relapsed or refractory CD20+ follicular B-cell non-Hodgkin's lymphoma (NHL).*	NOT RECOMMENDED: ibritumomab tiuxetan (Zevalin®) is not recommended for use within NHS Scotland for the preparation of a radiopharmaceutical incorporating Yttrium 90 [^{90}Y] for the treatment of adult patients with rituximab relapsed or refractory CD20+ follicular B-cell non-Hodgkin's lymphoma (NHL). The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
11.08.08 *SMC Report No. 449/08* NON SUBMISSION	ibritumomab tiuxetan 1.6mg/ml (Zevalin®) *Bayer plc* *Consolidation therapy after remission induction in previously untreated patients with follicular lymphoma.*	NOT RECOMMENDED: ibritumomab tiuxetan (Zevalin) is not recommended for use within NHS Scotland as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.02.06 *SMC Report No. 233/06* NEW PRODUCT (abbreviated submission)	ibuprofen intravenous injection 5mg/ml (Pedea®) *Orphan Europe (UK) Ltd* *Treatment of haemodynamically significant patent ductus arteriosus in pre-term newborn infants of less than 34 weeks gestational age.*	Accepted for use: ibuprofen intravenous injection 5mg/ml (Pedea®) is accepted for use within NHSScotland for the treatment of haemodynamically significant patent ductus arteriosus in pre-term newborn infants of less than 34 weeks gestational age. Safety and efficacy compared to existing alternative treatments has not been formally assessed.	Added to the LJF for Children as second choice for the treatment of closure of the ductus arteriosus. FC September 2006
12.03.12 *SMC Report No. 476/08* RESUBMISSION Patient Access Scheme	icatibant acetate 30mg solution for injection in pre-filled syringes (Firazyr®) *Shire Human Genetic Therapies* *The symptomatic treatment of acute attacks of hereditary angioedema in adults (with C1-esterase-inhibitor deficiency).*	Accepted for use: icatibant acetate (Firazyr®) is accepted for use within NHS Scotland for the symptomatic treatment of acute attacks of hereditary angioedema in adults (with C1-esterase-inhibitor deficiency). Icatibant treatment resulted in symptom relief in patients suffering acute abdominal, cutaneous and/or laryngeal attacks of hereditary angioedema. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of icatibant. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012
13.08.07 *SMC Report No. 391/07*	idursulfase 2mg/mL concentrate for solution for infusion (Elaprase®) *Shire HGT UK Ltd* *For the long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II).*	NOT RECOMMENDED: idursulfase (Elaprase®) is not recommended for use within NHS Scotland for the long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Idursulfase was approved by the EMEA under exceptional circumstances and has been designated an orphan medicinal product. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and, in addition, they did not present a sufficiently robust economic analysis.	NOT RECOMMENDED
12.12.05 *SMC Report No. 219/05*	iloprost trometamol nebuliser solution (Ventavis®) *Schering Health Care* *Treatment of patients with New York Heart Association Class III primary pulmonary hypertension as a second-line treatment where bosentan is ineffective or is not tolerated.*	Restricted use: iloprost trometamol nebuliser solution (Ventavis®) is accepted for restricted use within NHS Scotland for the treatment of patients with New York Heart Association Class III primary pulmonary hypertension as a second-line treatment where bosentan is ineffective or is not tolerated. It is an orphan product and efficacy data are very limited. Iloprost should also be restricted to use only as an alternative in patients receiving other forms of prostacyclin treatment. It is not recommended for patients who would not otherwise have received prostacyclin treatment because it is not cost effective in this situation. It is further restricted only to use by Specialists working in the Scottish Pulmonary Vascular Unit.	Added to the Additional List, only if initiated by specialists working in the Scottish Pulmonary Vascular Unit. FC April 2008
08.03.02 *SMC Report No. 01/02* and 10.01.03 *SMC Report No. 26/02*	imatinib (Glivec®) *Novartis* *Treatment of chronic myeloid leukaemia under the overall supervision of haematologists/oncologists.*	Restricted use: imatinib (Glivec®) is recommended for restricted use within the NHS in Scotland. Imatinib is the first treatment to offer major cytogenetic responses in chronic myeloid leukaemia. This approach appears to provide a significant advance in the treatment of a hitherto fatal haematological malignancy. This licence extension has been granted on the basis of interim analyses which show superiority of imatinib over interferon combination therapy in terms of cytogenetic and haematological response. Imatinib should be used only by or under the direction of haematologists/oncologists experienced in this field. There should be a formal process of audit and monitoring with a central registry of all patients receiving it and/or entry into a clinical trial.	Approved for use - added to the Additional List. FC January 2003
09.08.03 *SMC Report No. 08/02*	imatinib (Glivec®) *Novartis* *Gastrointestinal stromal tumours.*	Restricted use: imatinib (Glivec®) is recommended for restricted use within the NHS in Scotland, under the supervision of an oncologist for patients with Kit-positive gastrointestinal stromal tumours (GIST).	Approved for use - added to the Additional List.

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.12.07 *SMC Report No. 426/07* NON SUBMISSION	imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* *Treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) as monotherapy.*	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) as monotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.12.07 *SMC Report No. 427/07* NON SUBMISSION	imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* *Treatment of adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (PH + ALL) in combination with chemotherapy.*	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (PH + ALL) in combination with chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.12.07 *SMC Report No. 428/07* NON SUBMISSION	imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* *Treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet -derived growth factor receptor (PDGFR) gene re-arrangements.*	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.12.07 *SMC Report No. 429/07* NON SUBMISSION	imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* *Treatment of adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement.*	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.12.07 *SMC Report No. 430/07* NON SUBMISSION	imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* *Treatment of adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery.*	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.12.09 *SMC Report No*: *584/09* RESUBMISSION	imatinib 100mg and 400mg film-coated tablets (Glivec®) Novartis Pharmaceuticals UK Ltd *Adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.*	Restricted use: imatinib (Glivec®) is accepted for restricted use within NHS Scotland. Indication under review: adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. SMC restriction: Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria). Imatinib, given for a period of one year, significantly improved the estimated one year recurrence-free survival compared with placebo and was associated with an increase of 16.4 months in median time to recurrence in patients at high risk of relapse following resection. The economic case was demonstrated for a one-year adjuvant treatment duration only.	Added to the Additional List, Specialist Use only FC April 2011
09.04.12 *SMC Report No*: *584/09* 2nd RESUBMISSION	imatinib 100mg and 400mg film-coated tablets (Glivec®) Novartis Pharmaceuticals UK Ltd *Adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.*	Restricted use: imatinib (Glivec®) is accepted for restricted use within NHS Scotland. Indication under review: adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. SMC restriction: Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria). Adjuvant imatinib therapy given for a period of three years compared to one year, significantly improved the recurrence free survival in adult patients at significant risk of relapse following resection of GIST. The clinical and cost-effectiveness of three years adjuvant imatinib treatment was demonstrated.	**Included** on the Additional List for the indication in question. Specialist Use only. FC July 2012 See SMC advice above. Same SMC Report Number – this advice relates to an extension in treatment length to 3 years.
07.10.13 *SMC Report No. 923/13* NON SUBMISSION	imatinib (Glivec®) 100 mg / 400 mg film coated tablets *Novartis Pharmaceuticals UK Ltd* *Treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.*	NOT RECOMMENDED: imatinib (Glivec®) is not recommended for use within NHS Scotland for the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.05.05 *SMC Report No. 167/05*	imiquimod 5% cream (Aldara®) *3M Health Care* *Topical treatment of small superficial Basal Cell Carcinoma in adult patients in whom standard treatment with surgery or cryotherapy is contraindicated.*	Restricted use: imiquimod 5% (Aldara®) is accepted for restricted use within NHS Scotland for the topical treatment of small superficial Basal Cell Carcinoma in adult patients in whom standard treatment with surgery or cryotherapy is contraindicated. Its use should be supervised by specialists in dermatology. At 12 weeks post treatment the composite clearance rates in the randomised controlled trials were between 73-77% and initial clearance rates in the open label studies were between 90-94%. There is only limited follow-up data beyond 12 months.	Added to the LJF as a Prescribing Note. FC September 2005

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
12.05.08 *SMC Report No. 385/07* RESUBMISSION	imiquimod 5% cream (Aldara®) *Meda Pharmaceuticals Ltd* *Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate.*	Restricted use: imiquimod (Aldara®) is accepted for restricted use within NHS Scotland for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate. It should be restricted to use in patients after specialist advice. Imiquimod was more effective than vehicle in clearing actinic keratosis lesions.	**Included** on the LJF as a prescribing note, for Specialist Initiation, for the indication in question. FC November 2013
09.12.13 *SMC Report No. 934/13* NON SUBMISSION	imiquimod (Zyclara®) 3.75% cream *Meda Pharmaceuticals* *Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.*	NOT RECOMMENDED: imiquimod (Zyclara®) is not recommended for use within NHS Scotland for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.08.10 *SMC Report No. 619/10*	indacaterol 150 and 300 micrograms inhalation powder hard capsules (Onbrez Breezhaler®) *Novartis Pharmaceuticals Ltd* *For maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).*	Accepted for use: indacaterol (Onbrez Breezhaler®) is accepted for use within NHS Scotland. Indication under review: maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). Indacaterol has been found to be statistically superior to placebo and other long-acting bronchodilators in improving lung function (FEV1) after 12 weeks. Another long-acting beta2 agonist is available at lower cost.	Included on the LJF as a prescribing note. FC March 2013
07.05.07 *SMC Report No. 318/06*	infliximab 100mg powder for intravenous infusion (Remicade®) *Schering-Plough UK Ltd* *Treatment of severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant of other systemic therapy including ciclosporin, methotrexate or psoralen ultraviolet A (PUVA).*	Restricted use: infliximab (Remicade®) is accepted for restricted use within NHS Scotland for the treatment of severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant of other systemic therapy including ciclosporin, methotrexate or psoralen ultraviolet A (PUVA). Infliximab, compared to placebo, improves both signs and symptoms of psoriasis and quality of life in adults with plaque psoriasis. The economic case was demonstrated when used for patients with severe psoriasis who achieve a PASI 75 response or a 50% reduction in PASI and a 5 point reduction in DLQI from baseline at 10 weeks. It is one of several biologic interventions for the treatment of plaque psoriasis, some of which have lower drug acquisition costs.	Added to the Additional List. FC November 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
May 2009 *NICE MTA 187* *Supersedes SMC Report No. 363/07*	infliximab 100mg powder for intravenous infusion (Remicade®) *Schering-Plough UK Ltd* *Maintenance treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.*	Infliximab within its licensed indications is recommended as maintenance treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.	Added to the Additional List for Specialist Use only. FC September 2010
May 2009 *NICE MTA 187* *Supersedes SMC Report No. 364/07*	infliximab 100mg powder for intravenous infusion (Remicade®) *Schering-Plough UK Ltd* *Maintenance treatment of fistulising, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).*	Infliximab within its licensed indications is recommended as maintenance treatment of fistulising, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).	Added to the Additional List for Specialist Use only. FC September 2010
12.05.14 *SMC Report No. 374/07* RESUBMISSION	infliximab 100mg powder for concentrate solution for infusion (Remicade®) *Merck, Sharp & Dohme Ltd* *Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.*	NOT RECOMMENDED: infliximab (Remicade®) is not recommended for use within NHS Scotland for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies In two randomised controlled studies, infliximab 5mg/kg intravenous infusion on weeks 0, 2 and 6 was significantly superior to placebo for the endpoint of clinical response at week eight. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
10.10.05 *SMC Report No. 101/04* RESUBMISSION	infliximab 100mg vial of powder for intravenous infusion (Remicade®) *Schering-Plough* *Resubmission for new indication: severe ankylosing spondylitis inadequately controlled by conventional therapy.*	Restricted use: infliximab (Remicade®) is accepted for restricted use within NHS Scotland for the treatment of ankylosing spondylitis in patients who have severe axial symptoms, elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy. Infliximab has demonstrated improvements in signs and symptoms, quality of life and physical functioning and also reductions in spinal inflammation activity. As yet the magnitude of any effect on disease prognosis is unclear the treatment provides value for money only where clear and rigorous stopping rules are followed. It is restricted to use in accordance with British Society of Rheumatology (BSR) guidelines of July 2004.	Added to the Formulary as second choice for the treatment of ankylosing spondylitis, for Specialist Use only. FC January 2006

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
10.03.08 *SMC Report No. 448/08*	infliximab 100mg powder for concentrate for solution for infusion. (Remicade®) *Schering-Plough* *Treatment of severe, active Crohn's disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. Infliximab has been studied only in combination with conventional immunosuppressive therapy.*	Accepted for use: infliximab (Remicade®) is accepted for use within NHS Scotland for the treatment of severe, active Crohn's disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. In an open label study 88% of patients had a clinical response following the induction regimen and this was maintained at one year in significantly more patients receiving infliximab every 8 weeks compared with every 12 weeks.	Previously approved as an' off label medicine' for this indication in May 2007. Added to the Additional List, for use in paediatrics. FC May 2009
10.10.11 *SMC Report No. 739/11* NON SUBMISSION	infliximab (Remicade®) 100 mg powder for concentrate for solution for infusion *Merck Sharp & Dohme Ltd* *Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.*	NOT RECOMMENDED: infliximab (Remicade®) is not recommended for use within NHS Scotland. Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. Following NHS Quality Improvement Scotland's endorsement of the National Institute for Health and Clinical Excellence (NICE) multiple technology appraisal guidance No 187, infliximab is recommended as a treatment option in severe active Crohn's disease.	NOT RECOMMENDED
11.03.13 *SMC Report No. 854/13*	infliximab 100mg powder for concentrate for solution for infusion (Remicade®) *Merck Sharp & Dohme Limited* *Treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.*	Restricted use: infliximab (Remicade®) is accepted for restricted use within NHS Scotland for the treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies SMC restriction: as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory. Open-label, uncontrolled data indicate that infliximab induces remission of moderate to severe active ulcerative colitis in paediatric patients.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine. FC April 2013
11.03.13 *SMC Report No. 851/13*	ingenol mebutate, 150 & 500micrograms/g, gel (Picato®) *Leo Laboratories* *Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.*	Accepted for use: ingenol mebutate (Picato®) is accepted for use within NHS Scotland for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults. In four randomised, double-blind, phase III studies, a significantly greater proportion of adults with actinic keratosis (AK) achieved complete clearance when treated with ingenol mebutate gel compared with vehicle control.	**Included** on the LJF as a second choice drug, for the indication in question. FC November 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.09.06 *SMC Report No. 254/06*	inhaled insulin, 1mg and 3mg inhalation powder (Exubera®) *Pfizer* *Treatment of adult patients with type 2 diabetes mellitus not adequately controlled with oral antidiabetic agents and requiring insulin therapy or for the treatment of adult patients with type 1 diabetes mellitus, in addition to long or intermediate acting subcutaneous insulin, for whom the potential benefits of adding inhaled insulin outweigh the potential safety concerns.*	NOT RECOMMENDED: inhaled insulin (Exubera®) is not recommended for use within NHS Scotland for the treatment of adult patients with type 2 diabetes mellitus not adequately controlled with oral antidiabetic agents and requiring insulin therapy or for the treatment of adult patients with type 1 diabetes mellitus, in addition to long or intermediate acting subcutaneous insulin, for whom the potential benefits of adding inhaled insulin outweigh the potential safety concerns. The economic case has not been demonstrated.	NOT RECOMMENDED WITHDRAWN FROM THE MARKET
10.03.14 *SMC Report No. 856/13* RESUBMISSION	insulin degludec (Tresiba®) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen *Novo Nordisk* *Treatment of diabetes mellitus in adults.*	NOT RECOMMENDED: insulin degludec (Tresiba®) is not recommended for use within NHS Scotland for the treatment of diabetes mellitus in adults. Insulin degludec is non-inferior to other long-acting insulin analogues for treatment of type 1 and type 2 diabetes mellitus in adults assessed via glycosylated haemoglobin (HbA1c). The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
09.08.04 *SMC Report No. 110/04*	insulin detemir (Levemir®) *Novo Nordisk* *Treatment of diabetes mellitus.*	Restricted use: insulin detemir is accepted for restricted use within NHS Scotland for the treatment of diabetes mellitus. Insulin detemir is an acceptable basal insulin for patients with diabetes mellitus. Its use should be targeted on patients attempting to achieve better hypoglycaemic control as there may be some benefit related to a reduced intra-individual variation in glycaemic profile for insulin detemir compared with established insulins. It appears to be cost effective from the base-case of economic modelling, but this is limited by the degree of extrapolation involved and the associated width of the confidence intervals.	Added to the LJF as a Prescribing Note. FC August 2004
13.06.05 *SMC Report No. 138/04* PRODUCT UPDATE (abbreviated submission)	insulin detemir (Levemir®) *Novo Nordisk Ltd* *Treatment of children and adolescents with diabetes mellitus.*	Restricted use: insulin detemir is accepted for restricted use in Scotland in the treatment of children and adolescents with diabetes mellitus. The licence has been extended to include these patient groups and the restriction reflects similar advice from the Scottish Medicines Consortium (August 2004) when insulin detemir was reviewed as a new product for adult patients only.	Added to the LJF for Children. FC August 2005
13.08.07 *SMC Report No. 393/07* PRODUCT UPDATE (abbreviated submission)	insulin detemir, 100 U/ml solution for injection via InnoLet® device (Levemir® in InnoLet®) *Novo Nordisk Ltd* *Treatment of diabetes mellitus in patients for whom insulin detemir is an appropriate choice of insulin and who have poor visual acuity and dexterity problems.*	Restricted use: insulin detemir (Levemir®) for injection via the InnoLet® device is accepted for restricted use within NHS Scotland for treatment of diabetes mellitus in patients for whom insulin detemir is an appropriate choice of insulin and who have poor visual acuity and dexterity problems. The Scottish Medicines Consortium has previously advised that insulin detemir should be restricted to patients attempting to achieve better hypoglycaemic control as there may be some benefit related to a reduced intra-individual variation in glycaemic profile for insulin detemir compared with established insulins.	New formulation of a drug already included in the Formulary. FC October 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
14.05.12 *SMC Report No. 780/12* PRODUCT UPDATE (abbreviated submission)	insulin detemir (Levemir®) *NovoNordisk* *Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.*	Restricted use: insulin detemir (Levemir®) is accepted for restricted use within NHS Scotland for the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. SMC restriction: in patients unable to achieve good glycaemic control with established insulins. Insulin detemir has previously been accepted for restricted use by SMC in adults, adolescents and children from 6 years of age. Insulin detemir is included in the British National Formulary for Children 2011-2012.	**Included** on the LJF for the indication in question. Added to the LJF for Children. FC May 2012
04.10.02 *SMC Report No. 11/02*	insulin glargine (Lantus®) *Aventis* *Diabetes mellitus.*	Restricted use: insulin glargine (Lantus®) is recommended for restricted use within the NHS Scotland. Insulin glargine is an acceptable treatment for patients with diabetes mellitus. Pending further studies, its use should be targeted on patients who are at risk or experience unacceptable frequency and/or severity or nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. At present the evidence does not support its routine use in patients with type 2 diabetes unless they suffer from recurrent episodes of hypoglycaemia or require assistance with their insulin injections.	Approved for use - added to the Adult Formulary and the LJF for Children. FC May 2003
07.04.08 *SMC Report No. 456/08* PRODUCT UPDATE (abbreviated submission)	insulin glargine 100 units/ml solution for injection in a pre-filled pen (Lantus® SoloStar®) *Sanofi-aventis* *Treatment of adults, adolescents and children of 6 years or above with diabetes mellitus, where treatment with insulin is required.*	Restricted use: insulin glargine 100 units/ml solution for injection in a pre-filled pen (Lantus®SoloStar) is accepted for restricted use in the treatment of adults, adolescents and children of 6 years or above with diabetes mellitus, where treatment with insulin is required. It may be used in patients in whom treatment with this insulin analogue is appropriate and in whom the use of a pre-filled pen offers advantages over a pen and cartridge device. The use of insulin glargine should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections.	New formulation of a drug already in the Formulary. FC April 2008
08.04.13 *SMC Report No. 860/13* PRODUCT UPDATE (abbreviated submission)	insulin glargine 100units/ml solution for injection in a vial, cartridge, pre-filled pen (Lantus®, Clikstar®, Lantus®Solostar®) *Sanofi* *Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.*	Restricted use: insulin glargine is accepted for restricted use within NHS Scotland for the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. SMC restriction: patients in whom treatment with an insulin analogue is appropriate. Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections. The pre-filled pen has previously been accepted for restricted use in patients from the age of 6 years and above.	**Included** on the LJF for the indication in question. FC April 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
10.11.08 *SMC Report No. 512/08* PRODUCT UPDATE (abbreviated submission)	insulin glulisine solution for subcutaneous injection 100 units/ml (Apidra®) *Sanofi-aventis* *The treatment of adolescents and children, 6 years or older with diabetes mellitus, where treatment with insulin is required and for whom the use of a short-acting insulin analogue is appropriate.*	Restricted use: insulin glulisine (Apidra®) is accepted for restricted use within NHS Scotland for the treatment of adolescents and children, 6 years or older with diabetes mellitus, where treatment with insulin is required and for whom the use of a short-acting insulin analogue is appropriate. Insulin glulisine has a similar efficacy to other short-acting insulins in reducing glycated haemoglobin and a similar pharmacokinetic profile to at least one other insulin analogue. It is restricted to use in patients where soluble human insulin is inappropriate. The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults.	Added to the Formulary. FC October 2008
11.09.06 *SMC Report No. 298/06*	insulin glulisine for subcutaneous injection 100 units/ml (Apidra®) *Sanofi Aventis* *Treatment of adult patients with diabetes mellitus in whom treatment with a short-acting insulin analogue is appropriate.*	Restricted use: insulin glulisine (Apidra®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with diabetes mellitus in whom treatment with a short-acting insulin analogue is appropriate. Insulin glulisine has similar efficacy to other short-acting insulins in reducing glycated haemoglobin and a similar pharmacokinetic profile to at least one other insulin analogue. It is restricted to use in patients where regular human insulin is inappropriate.	Added to the Formulary. FC October 2008
07.04.08 *SMC Report No. 457/08* PRODUCT UPDATE (abbreviated submission)	insulin glulisine 100 units/ml solution for injection in a pre-filled pen (Apidra® SoloStar®) *Sanofi-aventis* *Treatment of adult patients with diabetes mellitus in whom treatment with this insulin analogue is appropriate.*	Restricted use: insulin glulisine 100 units/ml solution for injection in a pre-filled pen (Apidra® Solostar®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with diabetes mellitus in whom treatment with this insulin analogue is appropriate and in whom the use of a pre-filled pen offers advantages over a pen and cartridge device. Insulin glulisine has similar efficacy to other short-acting insulins in reducing glycated haemoglobin and a similar pharmacokinetic profile to at least one other insulin analogue. It is restricted to use in patients where regular human insulin is inappropriate.	Added to the Formulary. FC October 2008
10.11.08 *SMC Report No. 509/08* PRODUCT UPDATE (abbreviated submission)	insulin lispro 100 units/ml suspension for injection consisting of insulin lispro 25% and insulin lispro protamine 75% (Humalog® Mix25 KwikPen) and insulin lispro 100 units/ml suspension for injection consisting of insulin lispro 50% and insulin lispro protamine 50% (Humalog® Mix50 KwikPen) *Lilly UK* *The treatment of patients with diabetes mellitus who require insulin for maintenance of normal glucose homeostasis, for whom treatment with this biphasic insulin analogue is appropriate.*	Accepted for use: insulin lispro (Humalog® Mix25 KwikPen) and insulin lispro (Humalog® Mix50 KwikPen) are accepted for use within NHS Scotland for the treatment of patients with diabetes mellitus who require insulin for maintenance of normal glucose homeostasis, for whom treatment with this biphasic insulin analogue is appropriate.	Added to the Formulary. FC November 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.11.08 *SMC Report No. 508/08* PRODUCT UPDATE (abbreviated submission)	insulin lispro 100 units/ml solution for injection in a pre-filled pen (Humalog® KwikPen) *Lilly UK* *The treatment of adults and children with diabetes mellitus who require insulin for maintenance of normal glucose homeostasis, and for the initial stabilisation of diabetes mellitus.*	Accepted for use: insulin lispro (Humalog® KwikPen) is accepted for use within NHS Scotland for the treatment of adults and children with diabetes mellitus who require insulin for maintenance of normal glucose homeostasis, and for the initial stabilisation of diabetes mellitus. It may be used in patients for whom treatment with this short-acting insulin analogue is appropriate.	Added to the Formulary. FC November 2008
12.06.06 *SMC Report No. 258/06*	interferon alfa 2b (Viraferon® and Intron A®) 18 million IU, solution for injection, multidose pen in combination with ribavirin (Rebetol®) capsules 200mg *Schering Plough* *Treatment of children and adolescents 3 years of age and older, who have chronic hepatitis C, not previously treated, without liver decompensation and who are positive for serum HCV-RNA.*	Accepted for use: interferon alfa 2b (Viraferon® and Intron A®) in combination with ribavirin (Rebetol®) is accepted for use within NHS Scotland for the treatment of children and adolescents 3 years of age and older, who have chronic hepatitis C, not previously treated, without liver decompensation and who are positive for serum HCV-RNA. The combination is effective in eliminating hepatitis C virus in children and adolescents. The decision to treat should be made on a case by case basis, taking into account any evidence of disease progression such as hepatic inflammation and fibrosis, as well as prognostic factors for response, HCV genotype and viral load. The expected benefit of treatment should be weighted against the safety findings observed for paediatric subjects in the clinical trials.	Added to the Additional List. FC March 2007
12.11.12 *SMC Report No. 825/12* NON SUBMISSION	interferon beta-1a (Rebif®) *Merck Serono* *Patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.*	NOT RECOMMENDED: interferon beta-1a (Rebif®) is not recommended for use within NHS Scotland for patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.02.07 *SMC Report No. 345/07*	interferon beta-1b 250micrograms/mL for solution for injection (Betaferon®) *Schering Health Care Ltd* *Treatment of patients with a single demyelinating event with an active inflammatory process, severe enough to warrant treatment with intravenous corticosteroids, where alternative diagnoses are excluded and who are determined to be at high risk of developing clinically definite multiple sclerosis.*	NOT RECOMMENDED: interferon beta-1b (Betaferon®) is not recommended for use within NHS Scotland for the treatment of patients with a single demyelinating event with an active inflammatory process, severe enough to warrant treatment with intravenous corticosteroids, where alternative diagnoses are excluded and who are determined to be at high risk of developing clinically definite multiple sclerosis. Although interferon beta-1b has been found to increase the time to clinically definite multiple sclerosis over 2 years, the long-term effect on the disease process remains unknown. The economic case has not been demonstrated.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
08.04.13 *SMC Report No. 779/12* RESUBMISSION Patient Access Scheme	ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) *Bristol-Myers Squibb* *Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.*	Accepted for use: ipilimumab (Yervoy®) is accepted for use within NHS Scotland for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. Ipilimumab demonstrated a survival benefit over an investigational glycoprotein100 peptide vaccine in previously treated patients with advanced melanoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ipilumumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	**Included on** the Additional List, Specialist Use only, for the indication in question. FC June 2013
09.05.03 *SMC Report No. 38/03*	irbesartan (Aprovel®) *Sanofi-Synthelabo & Bristol-Myers Squibb* *Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus, as an alternative in patients unable to tolerate an ACE inhibitor.*	Restricted use: irbesartan (Aprovel®) is recommended for restricted use within NHS Scotland. Irbesartan, for the treatment of renal disease in patients with hypertension and type 2 diabetes mellitus, is effective, but has not been shown to be any more effective than ACE inhibitors, which are generally less expensive products, and for which there is a strong evidence base in diabetic renal disease and other forms of cardiovascular disease. Therefore, irbesartan should be considered, along with other angiotensin II antagonists licensed for diabetic renal disease, as an alternative in patients unable to tolerate an ACE inhibitor.	Approved for use - LJF Cardiovascular Working Group to establish its place in the Formulary. FC May 2003
09.05.11 *SMC Report No. 697/11*	iron isomaltoside 1000, 100mg/mL solution for injection/infusion (Monofer®) *Pharmacosmos UK* *Treatment of iron deficiency anaemia in the following conditions:* *•When oral iron preparations are ineffective or cannot be used;* *•Where there is a clinical need to deliver iron rapidly.* *The diagnosis of iron deficiency anaemia should be based on appropriate laboratory tests (e.g. serum ferritin, serum iron, transferrin saturation or hypochromic red cells).*	Restricted use: iron isomaltoside 1000 (Monofer®) is accepted for restricted use within NHS Scotland. Indication under review: Treatment of iron deficiency anaemia in the following conditions: • When oral iron preparations are ineffective or cannot be used; • Where there is a clinical need to deliver iron rapidly. SMC restriction: use is restricted to administration by high dose infusion within the licensed indication but excluding use in patients receiving haemodialysis. The manufacturer's economic case did not consider the cost-effectiveness of iv bolus administration or use in haemodialysis patients. Efficacy data are limited to two small open-label non comparative studies in patients with chronic kidney disease and chronic heart failure. Haemoglobin levels significantly increased from baseline in one study only.	**Included** on Lothian Joint Formulary for the indication in question. Added to the LJF as a first choice drug. Specialist Use only, FC May 2012 Restricted to Renal and Reproductive Medicine patient groups only FC November 2013
12.03.07 *SMC Report No. 319/06* RESUBMISSION	ivabradine 5mg, 7.5mg tablets (Procoralan®) *Servier Laboratories Limited* *Symptomatic treatment of chronic stable angina in patients with normal sinus rhythm who have a contra-indication or intolerance for beta-blockers.*	Restricted use: ivabradine (Procoralan®) is accepted for restricted use within NHS Scotland for the symptomatic treatment of chronic stable angina pectoris in patients with normal sinus rhythm for whom heart rate control is desirable and who have a contra-indication or intolerance for beta-blockers and rate-limiting calcium-channel blockers. Non-inferiority of ivabradine versus a beta blocker and a calcium-channel blocker was shown in two controlled trials. Long-term protection against cardiovascular events, however, has not been demonstrated.	Added to the LJF as a prescribing note, initiation by specialists only, prescribing in primary care. FC September 2007

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07.02.11 *SMC Report No. 689/11* NON SUBMISSION	ivabradine (Procoralan®) 5mg and 7.5 mg film coated tablets *Servier Laboratories Ltd* *Symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm, in combination with beta-blockers, in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.*	NOT RECOMMENDED: ivabradine (Procoralan®) is not recommended for use within NHS Scotland. Indication under review: Symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm, in combination with beta-blockers, in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.10.12 *SMC Report No. 805/12*	ivabradine 5 and 7.5mg film-coated tablets (Procoralan®) *Servier Laboratories Ltd* *Chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 beats per minute (bpm), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated.*	Restricted use: ivabradine (Procoralan®) is accepted for restricted use within NHS Scotland Chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 beats per minute (bpm), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated. SMC restriction: for initiation only in patients whose resting heart rate remains ≥75 beats per minute despite optimal standard therapy. In a post-hoc subgroup analysis of the pivotal study in patients meeting the licensed indication, ivabradine was significantly more effective than placebo at reducing the risk of a composite of cardiovascular death or hospitalisation for worsening heart failure. However, in patients on the target dose of beta-blocker, ivabradine was not significantly more effective.	**Included** on the LJF as a prescribing note for the indication in question. FC November 2012
10.06.13 *SMC Report No. 827/12* RESUBMISSION	ivacaftor 150mg film-coated tablets (Kalydeco®) *Vertex Pharmaceuticals UK Ltd* *Treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.*	NOT RECOMMENDED: ivacaftor (Kalydeco®) is not recommended for use within NHS Scotland for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Ivacaftor has demonstrated superiority over placebo measured by absolute change in forced expiratory volume in one second (FEV1) % predicted in two phase III, double-blind randomised studies. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic assessment to gain acceptance by SMC.	NOT RECOMMENDED
12.07.10 *SMC Report No. 606/10*	ketoprofen/omeprazole, 100mg/20mg; 200mg/20mg modified release capsules (Axorid®) *Meda Pharmaceuticals* *Symptomatic treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis in patients with a previous history or who are at risk of developing NSAID associated gastric ulcers, duodenal ulcers and gastroduodenal erosions in whom continued treatment with ketoprofen is essential.*	Accepted for use: ketoprofen/omeprazole (Axorid®) is accepted for use within NHS Scotland. Licensed indication under review: the symptomatic treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis in patients with a previous history or who are at risk of developing NSAID associated gastric ulcers, duodenal ulcers and gastroduodenal erosions in whom continued treatment with ketoprofen is essential. Studies in healthy volunteers demonstrated the bioequivalence of this combination product to the reference products, modified-release ketoprofen and omeprazole. Other nonsteroidal anti-inflammatory drugs can be co-prescribed with proton pump inhibitors at lower cost.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012

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10.11.03 *SMC Report No. 65/03* NON SUBMISSION	ketotifen hydrogen fumarate (Zaditen® Eye Drops) *Novartis* *Symptomatic treatment of seasonal allergic conjunctivitis.*	NOT RECOMMENDED: In the absence of a submission to SMC from the licence holder, ketotifen hydrogen fumarate (Zaditen® Eye Drops) is not recommended for use within NHS Scotland for the symptomatic treatment of seasonal allergic conjunctivitis.	NOT RECOMMENDED
09.02.09 *SMC Report No. 532/09*	lacosamide, 50mg, 100mg,150mg and 200mg tablets, 15mg/ml syrup and 10mg/ml solution for intravenous infusion (Vimpat®) *UCB Pharma Limited* *Treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older.*	Restricted use: lacosamide (Vimpat®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older. The proportion of responders was significantly greater with adjunctive lacosamide treatment compared to placebo. Lacosamide use is restricted to patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC May 2009
07.09.09 *SMC Report No. 569/09* PRODUCT UPDATE (abbreviated submission)	lamivudine/zidovudine fixed-dose combination (Combivir®) *GlaxoSmithKline UK Ltd* *Treatment of Human Immunodeficiency Virus Type 1 (HIV-1) in paediatric patients weighing 14kg to 30kg.*	Accepted for use: lamivudine/zidovudine fixed dose combination (Combivir®) in antiretroviral combination therapy is accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) in paediatric patients weighing 14kg to 30kg. This combination is listed in the British National Formulary for Children for the treatment of HIV infection. It was previously licensed for use in adults and adolescents weighing at least 30kg. The availability of both the combination product and its active ingredients pre-date the establishment of the Scottish Medicines Consortium.	Added to the Additional List, for Specialist Use only. FC September 2009
11.12.06 *SMC Report No. 231/06* NON SUBMISSION	lanreotide (Somatuline® LA) *Ipsen Ltd* *Treatment of thyrotrophic adenomas when the circulating level of thyroid stimulating hormone remains inappropriately high after surgery and/or radiotherapy.*	NOT RECOMMENDED: lanreotide (Somatuline® LA) is not recommended for use within NHSScotland for the treatment of thyrotrophic adenomas when the circulating level of thyroid stimulating hormone remains inappropriately high after surgery and/or radiotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.01.06 *SMC Report No. 229/05* PRODUCT UPDATE (abbreviated submission)	lansoprazole orodispersible tablet 15mg, 30mg (Zoton® FasTab®) *Wyeth* *In combination with appropriate antibiotics, for the eradication of Helicobacter pylori from the upper gastrointestinal tract in patients with ulcer-like dyspepsia in whom Helicobacter pylori infection has been demonstrated.*	Accepted for use: lansoprazole orodispersible tablet (Zoton® FasTab®) is accepted for use in NHS Scotland, in combination with appropriate antibiotics, for the eradication of *Helicobacter pylori* from the upper gastrointestinal tract in patients with ulcer-like dyspepsia in whom *Helicobacter pylori* infection has been demonstrated. The standard formulation of lansoprazole also has this indication.	Extension to licence of a drug already included in the Formulary.

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07.05.07 *SMC Report No. 286/06*	lanthanum carbonate 500, 750, 1000mg chewable tablets (Fosrenol®) *Shire Pharmaceuticals Contract Ltd* *As a phosphate-binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis.*	Restricted use: Lanthanum carbonate (Fosrenol®) is accepted for restricted use within NHS Scotland as a phosphate-binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis. Lanthanum carbonate is as effective as calcium carbonate in reducing phosphate to target levels. It is restricted to use as a second-line agent in patients where a non-aluminium, non-calcium phosphate binder is required.	Added to the Additional List for use in the control of hyperphosphataemia in chronic renal failure after calcium-based binders and sevelamer. FC March 2008
11.10.10 *SMC Report No. 640/10*	lanthanum carbonate, 500mg, 750mg, 1,000mg, chewable tablets (Fosrenol®) *Shire Pharmaceuticals Ltd* *Lanthanum carbonate is indicated as a phosphate binding agent for use in the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.* *Lanthanum is also indicated as a phosphate-binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis.*	NOT RECOMMENDED: lanthanum carbonate (Fosrenol®) is not recommended for use within NHS Scotland. Indication under review: as a phosphate binding agent for use in the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels. When compared with placebo, in patients with chronic kidney disease not yet on dialysis, more patients treated with lanthanum carbonate achieved a serum phosphate concentration ≤1.49mmol/L. The manufacturer did not present a sufficiently robust clinical or economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
10.12.12 *SMC Report No. 821/12* PRODUCT UPDATE (abbreviated submission)	lanthanum carbonate 750mg and 1000mg oral powder (Fosrenol®) *Shire Pharmaceuticals Contracts Ltd* *As a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).*	Restricted use: lanthanum carbonate oral powder (Fosrenol®) is accepted for restricted use in NHS Scotland as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Lanthanum is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥ 1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels. SMC restriction: as a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required. Lanthanum carbonate is as effective as calcium carbonate in reducing phosphate to target levels.	**Included** on the Additional List for the indication in question. FC December 2012

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13.07.10 *SMC Report No. 526/09* RESUBMISSION	lapatinib, 250mg film-coated tablets (Tyverb®) *GlaxoSmithKline* *In combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer.*	NOT RECOMMENDED: lapatinib (Tyverb®) is not recommended for use within NHS Scotland. Indication under review: in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have progressive disease following prior therapy including anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. In a randomised open-label study the median time to progression for lapatinib plus capecitabine was significantly longer than for capecitabine monotherapy. There was no statistically significant difference in overall survival. Compared with capecitabine monotherapy, the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. There was also uncertainty about the comparative effectiveness and cost-effectiveness compared to unlicensed use of trastuzumab and capecitabine in patients with metastatic disease confined to the central nervous system, itself a treatment of unproven cost-effectiveness.	NOT RECOMMENDED
13.02.12 *SMC Report No. 768/12* NON SUBMISSION	lapatinib (Tyverb®) 250 mg film-coated tablets *GlaxoSmithKline* *Treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor.*	NOT RECOMMENDED: lapatinib (Tyverb®) 250 mg film-coated tablets is not recommended for use within NHS Scotland for the Treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of lapatinib in this indication. However due to the significant time interval between product availability and the expected date of NICE guidance, not recommended advice has been issued. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.11.13 *SMC Report No. 925/13* NON SUBMISSION	lapatinib (Tyverb®) 250 mg film-coated tablets *GlaxoSmithKline* *Treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.*	NOT RECOMMENDED: lapatinib (Tyverb®) is not recommended for use within NHS Scotland for the treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.12.04 *SMC Report No. 100/04* RESUBMISSION	laronidase (Aldurazyme®) *Genzyme* *Treatment of Mucopolysaccharidosis I.*	NOT RECOMMENDED: laronidase is not recommended for use within NHS Scotland for the treatment of Mucopolysaccharidosis I. Laronidase was approved by the EMEA under exceptional circumstances and has been granted orphan drug status. No information is presented in the submission to support the therapy being cost effective.	NOT RECOMMENDED

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12.07.04 *SMC Report No. 102/04*	latanoprost (Xalatan®) *Pfizer* *Treatment of raised intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma.*	Restricted use: latanoprost (Xalatan®) is accepted for restricted use within NHS Scotland for the treatment of raised intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma. Use of latanoprost, as monotherapy, should be restricted to patients who have contraindications to beta-blockers or have a history of adverse reactions to this group of drugs. It may also be indicated in addition to beta-blockers when required. It is one of a number of topical ocular prostaglandin analogue preparations licensed in the UK for this indication. In reducing IOP it is comparable in effect to other drugs in its class.	Added to the Formulary.
14.01.08 *SMC Report No. 432/07* PRODUCT UPDATE (abbreviated submission)	latanoprost, timolol eyedrops (Xalacom®) *Pfizer Ltd* *Reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.*	Accepted for use: latanoprost, timolol (Xalacom®) is accepted for use within NHS Scotland for reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. This abbreviated submission relates to a licence extension to cover use of this medicine in patients insufficiently responsive to a prostaglandin analogue used alone. Xalacom® is suitable for patients in whom timolol and latanoprost are appropriate choices of beta-blocker and prostaglandin analogue respectively. It costs less than the individual preparations.	Added to the Additional List FC August 2008
08.07.13 SMC Report No. *879/13* PRODUCT UPDATE (abbreviated submission)	latanoprost 50microgram/mL preservative-free single-dose eye-drops (Monopost®) *Spectrum Thea Pharmaceuticals Ltd* *For the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.*	Restricted use: latanoprost preservative-free eye-drops (Monopost®) are accepted for restricted use within NHS Scotland for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. SMC restriction: to use in patients who have proven sensitivity to the preservative benzalkonium chloride. SMC has previously accepted preserved latanoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent generic multi-dose eye drop preparation with preservative.	**Included** on the LJF as a prescribing note, Specialist initiation, for the indication in question. FC July 2013
07.04.14 *SMC Report No. 441/08* 2nd RESUBMISSION	lenalidomide, 7.5mg, 10mg, 15mg and 25mg hard capsules (Revlimid®) *Celgene Limited* *In combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy).*	Restricted use: lenalidomide (Revlimid®) is accepted for restricted use within NHS Scotland in combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy). SMC restriction: to use at first relapse in patients who have received prior therapy with bortezomib in whom thalidomide has not been tolerated or is contraindicated. Lenalidomide plus dexamethasone significantly increased the time to progression compared with dexamethasone alone in multiple myeloma patients who had been treated with at least one prior therapy. SMC has previously accepted lenalidomide for use in patients who have received at least two prior lines of therapy i.e. at second relapse. This advice now extends its use to patients at first relapse who received bortezomib as their one prior therapy.	For use in patients who have received at least two prior lines of therapy. Added to the Additional List, for Specialist Use only. FC September 2010 For patients who have received only one prior therapy - **Not included** on the LJF, pending protocol. FC July 2014

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10.03.14 *SMC Report No. 942/14*	lenalidomide 2.5mg, 5mg, and , 10mg, hard capsules (Revlimid®) *Celgene Ltd* *For the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.*	Accepted for use: lenalidomide (Revlimid®) is accepted for use within NHS Scotland for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate. Lenalidomide therapy significantly increased the proportion of patients achieving sustained red blood cell transfusion independence compared with best supportive care. However, there was no significant improvement in overall survival.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC April 2014
09.10.06 *SMC Report No. 315/06* PRODUCT UPDATE (abbreviated submission)	lercanidipine 20mg tablet (Zanidip®) *Recordati Pharmaceuticals* *Treatment of mild to moderate essential hypertension in patients for whom this is an appropriate antihypertensive agent.*	Accepted for use: lercanidipine 20mg tablet (Zanidip®) is accepted for use in NHS Scotland for the treatment of mild to moderate essential hypertension in patients for whom this is an appropriate antihypertensive agent. This new strength allows a reduction in the number of tablets administered at the maximum dose, at reduced cost compared with the formulation available previously.	'Not preferred' as suitable alternatives exist. FC December 2008
07.03.05 *SMC Report No. 152/05*	letrozole 2.5mg tablets (Femara®) *Novartis Pharmaceuticals (UK) Ltd* *Treatment of invasive early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy.*	Restricted use: letrozole (Femara®) is accepted for restricted use within NHS Scotland for the treatment of invasive early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy. Treatment should continue for 3 years or until tumour relapse, whichever occurs first. Following 5 years of adjuvant tamoxifen therapy the risk of recurrence (in ipsilateral breast, new tumour in contralateral breast or distance metastases) occurs at an aggregate rate of 2-3% per year. The use of letrozole as extended adjuvant treatment resulted in a 43% lower risk of recurrence compared with placebo. However, a significant difference for overall survival, defined as time to death from any cause, was seen in lymph-node positive patients only. Clinicians and patients should consider the residual risk of recurrence, individual preferences and the risks and benefits of treatment. Letrozole is restricted to initiation to breast cancer specialists.	Added to the Formulary as a Prescribing Note. Shared care protocol to be developed. FC August 2005
08.05.06 *SMC Report No. 251/06*	letrozole 2.5mg tablets (Femara®) *Novartis Pharmaceuticals UK Ltd* *Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer.*	Restricted use: letrozole (Femara®) is accepted for restricted use within NHS Scotland for the adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer. Letrozole has shown benefit over standard anti-oestrogen therapy in terms of disease-free survival, although a pre-planned sub-group analysis showed a statistically significant beneficial effect in node-positive but not node-negative patients. It offers an alternative to existing treatment and has a different range of adverse effects. Another aromatase inhibitor is available for the same indication at a lower cost. Treatment with letrozole should be initiated by a breast cancer specialist.	Added to the LJF as first choice for patients at risk of early recurrence or with a contraindication to tamoxifen. Letrozole also first choice for extended adjunvant treatment after 5 years treatment with tamoxifen. FC August 2010
10.01.05 *SMC Report No. 150/04* PRODUCT UPDATE (abbreviated submission)	levetiracetam (Keppra®) 750mg film-coated tablets *UCB Pharma Limited* *Additional dosage form for adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients for whom therapy is appropriate.*	Restricted use: levetiracetam 750mg film-coated tablets are accepted for restricted use in NHS Scotland as an additional dosage form for adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients for whom therapy is appropriate. Its use should be initiated by physicians who have appropriate experience in the treatment of epilepsy. The budget impact for NHS Scotland is likely to be small.	Added to the Formulary with other additional anti-epilepsy agents. FC March 2005

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10.01.05 *SMC Report No. 151/04* PRODUCT UPDATE (abbreviated submission)	levetiracetam (Keppra®) 100mg/ml oral solution *UCB Pharma Limited* *Additional dosage form for adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients for whom therapy is appropriate.*	Restricted use: levetiracetam 100 mg/ml oral solution is accepted for restricted use in NHS Scotland as an additional dosage form for adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients for whom therapy is appropriate. Its use should be initiated by physicians who have appropriate experience in the treatment of epilepsy. The budget impact for NHS Scotland is likely to be small.	Added to the Formulary with other additional anti-epilepsy agents. FC March 2005
09.10.06 *SMC Report No. 311/06* PRODUCT UPDATE (abbreviated submission)	levetiracetam 500mg/5ml concentrate for infusion (Keppra®) *UCB Pharma Ltd* *Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy.*	Accepted for use: levetiracetam 500mg/5ml concentrate for infusion (Keppra®) is accepted for use in NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. It is an alternative when oral administration is temporarily not feasible in patients for whom levetiracetam is an appropriate anticonvulsant. Intravenous infusion is associated with a greater cost per dose.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC January 2010
11.02.08 *SMC Report No. 394/07* RESUBMISSION	levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* *As adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 4 years of age with epilepsy.*	Accepted for use: levetiracetam (Keppra®) is accepted for use within NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 4 years of age with epilepsy. In the pivotal study, addition of levetiracetam to existing anticonvulsant therapy achieved a greater reduction in partial seizure frequency than addition of placebo.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC January 2010
11.02.08 *SMC Report No. 395/07* RESUBMISSION	levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* *As adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME).*	Accepted for use: levetiracetam (Keppra®) is accepted for use within NHS Scotland as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. In the pivotal study, addition of levetiracetam to existing anticonvulsant therapy was more effective than addition of placebo in reducing the number of days on which myoclonic seizures occurred.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC January 2010
11.02.08 *SMC Report No. 396/07* RESUBMISSION	levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* *As adjunctive therapy in the treatment of primary generalised tonic-clonic (PGTC) seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy.*	Accepted for use: levetiracetam (Keppra®) is accepted for use within NHS Scotland as adjunctive therapy in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with generalised idiopathic epilepsy. In the pivotal study, addition of levetiracetam to existing anticonvulsant therapy achieved a significantly greater reduction in the frequency of primary generalised tonic-clonic seizures than addition of placebo.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC January 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
11.02.08 *SMC Report No. 397/07* RESUBMISSION	levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* *As monotherapy, in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy.*	Restricted use: levetiracetam (Keppra®) is accepted for restricted use within NHS Scotland as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Levetiracetam has been shown to be non-inferior to an older first choice anti-epileptic drug for partial seizures. Levetiracetam is significantly more expensive than traditional drugs so its use is restricted to patients for whom the range of traditional drugs normally used for first-line treatment are ineffective or unsuitable.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC January 2010
17.01.11 *SMC Report No. 661/10* PRODUCT UPDATE (abbreviated submission)	levetiracetam 100mg/ml oral solution (Keppra®) *UCB Pharma Ltd* *Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children and infants from 1 month of age to 4 years with epilepsy.*	Restricted use: levetiracetam 100mg/ml oral solution (Keppra®) is accepted for restricted use within NHS Scotland. Indication under review: adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children and infants from 1 month of age to 4 years with epilepsy. SMC restriction: to initiation and management under the supervision of a paediatric neurologist. The Scottish Medicines Consortium has previously accepted this product for use within NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 4 years of age with epilepsy. Addition of levetiracetam to existing anticonvulsant therapy has shown a greater reduction in partial seizure frequency than addition of placebo. Levetiracetam is listed in the British National Formulary for Children 2010-2011 for adjunctive treatment for partial seizures with or without secondary generalisation from 1 month old. Smaller syringe sizes of 1 and 3 ml have been made available to accommodate the smaller volumes for younger children.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care. FC January 2011
09.01.04 *SMC Report No. 85/03* PRODUCT UPDATE (abbreviated submission)	levodopa, carbidopa and entacapone (Stalevo®) *Orion Pharma (UK) Ltd* *Treatment of patients with Parkinson's disease and end of dose motor fluctuations not stabilised on levodopa/dopa decarboxylase inhibitor treatment.*	Accepted for use: Stalevo® is accepted for use in NHSScotland for the treatment of patients with Parkinson's disease and end of dose motor fluctuations not stabilised on levodopa/dopa decarboxylase inhibitor treatment. This combination preparation allows administration of a single tablet incorporating ingredients that are routinely combined for the indication described above. This may improve convenience to the patient. Depending on the doses and formulations being replaced, conversion to the combination may result in a modest increase in cost or (less commonly) a cost saving.	Added to the Additional List, for general use. Should be beneficial to patients receiving the three drugs contained in this combination product. Should be reserved for patients already stable on three individual drugs at stated doses. FC March 2004
10.02.14 *SMC Report No. 938/14* PRODUCT UPDATE (abbreviated submission)	levonorgestrel 1500microgram tablet (Upostelle®) *Consilient Healthcare* *Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.*	Accepted for use: levonorgestrel (Upostelle®) is accepted for use within NHS Scotland as emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. When the use of emergency contraception is indicated this is a slightly cheaper alternative to an existing preparation.	**Included** on the LJF for the indication in question. The choice of product will be reviewed with the Working Group. FC February 2014

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11.08.08 *SMC Report No. 334/06* RESUBMISSION	lidocaine 5% plaster (Versatis®) *Grunenthal GmbH* *Treatment of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia).*	Restricted use: lidocaine 5% medicated plaster (Versatis®) is accepted for restricted use within NHS Scotland for the treatment of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia). There are only limited comparative data available for lidocaine plasters, the comparative clinical effectiveness remains unclear. It is restricted to use in patients who are intolerant of first-line systemic therapies for post-herpetic neuralgia or where these therapies have been ineffective.	Added to the Formulary as a 'Prescribing Note'. FC December 2008
09.06.08 *SMC Report No. 483/08* NON SUBMISSION	lidocaine 70mg / tetracaine 70mg (Rapydan 70 mg / 70 mg medicated plaster) *EUSA Pharma (Europe) Limited* *For surface anaesthesia of the skin in connection with needle puncture and in cases of superficial surgical procedures (such as excision of various skin lesions and punch biopsies) on normal skin in adults; or for surface anaesthesia of the skin in connection with needle puncture on normal intact skin in children from 3 years of age.*	NOT RECOMMENDED: lidocaine 70mg / tetracaine 70mg (Rapydan 70mg / 70mg medicated plaster) is not recommended for use within NHSScotland for surface anaesthesia of the skin in connection with needle puncture and in cases of superficial surgical procedures (such as excision of various skin lesions and punch biopsies) on normal skin in adults; or for surface anaesthesia of the skin in connection with needle puncture on normal intact skin in children from 3 years of age. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.06.13 *SMC Report No. 869/13*	linaclotide hard capsules, 290 micrograms (Constella®) *Almirall SA* *Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.*	Restricted use: linaclotide (Constella®) is accepted for restricted use within NHS Scotlandfor symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults. SMC restriction: linaclotide is restricted for use in patients with moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options. In two pivotal phase III studies linaclotide was superior to placebo for the co-primary endpoints of abdominal pain/discomfort responders and IBS degree-of-relief responders at 12 weeks. There are no comparative efficacy data versus first- or second-line treatments.	**Included** on the Additional List, for General Use on specialist's advice, for the indication in question. FC May 2014

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
16.01.12 *SMC Report No. 746/11*	linagliptin, 5mg film-coated tablet (Trajenta®) *Boehringer Ingelheim / Eli Lilly and Company Ltd* *For the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:* *As monotherapy* *- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contra-indicated due to renal impairment* *As combination therapy* *- in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control* *- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.*	Restricted Use: linagliptin film-coated tablet (Trajenta®) is accepted for restricted use within NHS Scotland. For the treatment of type 2 diabetes mellitus to improve glycaemic control in adults: As monotherapy - in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contra-indicated due to renal impairment As combination therapy - in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control - in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control SMC restriction: in combination therapy with metformin when diet and exercise plus metformin alone does not provide adequate glycaemic control in patients for whom the addition of a sulphonylurea is inappropriate. In two randomised double-blind, controlled studies, linagliptin in combination with metformin was found to be non-inferior to a sulphonylurea plus metformin, and superior to placebo plus metformin in controlling glycaemia, measured by the change in glycosylated haemoglobin (HbA1c). Linagliptin was associated with similar rates of hypoglycaemia and changes in weight when compared with placebo. Linagliptin is one of a number of medicines in this class, some of which are available at a lower acquisition cost. SMC cannot recommend the use of linagliptin as monotherapy or in combination with metformin and a sulphonylurea as the company's submission related only to its use in combination with metformin.	**Not included** on the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. The current LJF choice is sitagliptin. FC April 2013
11.02.13 *SMC Report No. 841/13* PRODUCT UPDATE (abbreviated submission)	linagliptin 2.5mg plus metformin 850mg and linagliptin 2.5mg plus metformin 1000mg film-coated tablets (Jentadueto®) *Boehringer Ingelheim* *Treatment of adult patients with type 2 diabetes mellitus.* *(see details in next column)*	Restricted use: linagliptin plus metformin tablets (Jentadueto®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with type 2 diabetes mellitus: • as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin. • in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. SMC restriction: to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and these fixed-doses are considered appropriate.	**Not included** on the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. Sitagliptin remains the LJF choice. FC January 2013

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11.02.13 *SMC Report No. 850/13*	linagliptin, 5mg film-coated tablets (Trajenta®) *Boehringer Ingelheim and Eli Lilly* *For the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as:* *- monotherapy* *- combination therapy.*	Restricted use: linagliptin (Trajenta®) is accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults: as monotherapy • in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment. as combination therapy • in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products does not provide adequate glycaemic control. • in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. SMC restriction: - as monotherapy in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance. - as combination therapy with a sulphonylurea and metformin when diet and exercise plus dual therapy does not provide adequate glycaemic control. Treatment with linagliptin reduces HbA1c levels significantly more than placebo when used as monotherapy or in combination with metformin and a sulphonylurea or in combination with insulin and/or metformin and/or pioglitazone. An indirect comparison demonstrated similar efficacy to another DPP-4 inhibitor. SMC is unable to recommend the use of linagliptin in combination with insulin as the economic case has not been demonstrated.	**Not included** on the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. The current LJF choice is sitagliptin. FC April 2013
07.04.14 *SMC Report No. 908/13*	lipegfilgrastim, 6mg, solution for injection (Lonquex®) *Teva Pharma BV* *Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).*	Restricted use: lipegfilgrastim (Lonquex®) is accepted for restricted use within NHS Scotland for reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). SMC restriction: where a long-acting granulocyte-colony-stimulating factor is appropriate. In a randomised, double-blind study, in adults with breast cancer given myelosuppressive chemotherapy associated with a high risk of febrile neutropenia, lipegfilgrastim was compared with another long-acting granulocyte colony-stimulating factor when used as primary prophylaxis against febrile neutropenia. The study found lipegfilgrastim was non-inferior to the comparator preparation in terms of the mean duration of severe neutropenia in the first chemotherapy cycle.	**Not included** on the LJF, pending protocol. FC July 2014
13.08.07 *SMC Report No. 164/05* RESUBMISSION	liposomal cytarabine 50mg suspension for injection (DepoCyte®) *Napp Pharmaceuticals* *For the intrathecal treatment of lymphomatous meningitis*	NOT RECOMMENDED: liposomal cytarabine suspension (DepoCyte®) is not recommended for use within NHS Scotland for the intrathecal treatment of lymphomatous meningitis. There is limited clinical evidence to support a claim of superior efficacy for liposomal cytarabine over existing therapy. Effects on symptom improvement and quality of life were not well defined. The manufacturer did not present a sufficiently robust economic analysis and its justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED

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07.12.09 *SMC Report No: 585/09*	liraglutide 6mg/mL prefilled pen for injection (3mL) (Victoza®) *Novo Nordisk Ltd*. *Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control:* *In combination with metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea;* *In combination with metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual*	Restricted Use: liraglutide (Victoza®) is accepted for restricted use within NHS Scotland. Licensed indication under review: Liraglutide for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control: - in combination with metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea; - in combination with metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy. Five randomised controlled studies have demonstrated efficacy of liraglutide against relevant comparators in terms of the primary endpoint, change from baseline in glycated haemoglobin (HbA1c) after 26 weeks of treatment. Restriction: Liraglutide is restricted to use as a third-line antidiabetic agent. The economic case for second-line use, added to metformin in place of a sulphonylurea, has not been demonstrated.	Included on the LJF as a prescribing note, for Specialist Initiation, for the indication in question FC November 2013
13.05.13 *SMC Report No: 863/13*	lisdexamfetamine dimesylate, 30mg, 50mg & 70mg capsules (Elvanse®) *Shire Pharmaceutical Contracts Ltd* *As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate.*	Accepted for use: lisdexamfetamine dimesylate (Elvanse®) is accepted for use within NHS Scotland as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate. In a multi-centre, randomised, double-blind, controlled study in children and adolescents with ADHD, treatment with lisdexamfetamine was associated with a shorter time to first response compared with a non-stimulant, centrally-acting sympathomimetic agent. A greater proportion of lisdexamfetamine treated patients achieved improvements in symptom scores and functioning than those treated with the active comparator.	**Included** on the Additional List and as a prescribing note, for the indication in question. FC July 2013
09.09.13 *SMC Report No: 903/13*	lixisenatide 10microgram/0.2mL, 20microgram/0.2mL solution for injection in pre-filled disposable pen (Lyxumia®) *Sanofi* *Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.*	Restricted use: lixisenatide (Lyxumia®) is accepted for restricted use within NHS Scotland for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: to use in patients for whom a glucagon-like protein-1 (GLP-1) agonist is appropriate, as an alternative to existing GLP-1 agonists. Lixisenatide reduces glycosylated haemoglobin (HbA1c) and body weight compared with placebo when used in combination with oral antidiabetic drugs or in combination with basal insulin.	**Included** on the LJF as a first choice drug, Specialist Initiation, for the indication in question. FC October 2013
10.02.14 *SMC Report No. 956/14* NON SUBMISSION	lomitapide (Lojuxta®) 5mg, 10 mg, 20mg hard capsules *Aegerion Phamaceuticals* *Adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis in adult patients with homozygous familial hypercholesterolaemia (HoFH).*	NOT RECOMMENDED: lomitapide (Lojuxta®) is not recommended for use within NHS Scotland as an adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis in adult patients with homozygous familial hypercholesterolaemia (HoFH). Genetic confirmation of HoFH should be obtained whenever possible. Other forms of primary hyperlipoproteinaemia and secondary causes of hypercholesterolaemia (e.g. nephrotic syndrome, hypothyroidism) must be excluded. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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13.11.06 *SMC Report No. 326/06* PRODUCT UPDATE (abbreviated submission)	lopinavir 200mg, ritonavir 50mg tablet (Kaletra®) *Abbott Laboratories Ltd* *Treatment of HIV-1 infected adults and children above the age of 2 years, in combination with other antiretroviral agents.*	Accepted for use: lopinavir 200 mg, ritonavir 50 mg tablet (Kaletra®) is accepted for use in NHS Scotland for the treatment of HIV-1 infected adults and children above the age of 2 years, in combination with other antiretroviral agents. For patients for whom this drug combination is appropriate, it is associated with a reduced pill burden compared to an existing solid oral dose formulation containing these drugs at no increased cost.	Additional List to be amended - lopinavir with ritonavir capsules to be replaced with the new formulation of Kaletra®. FC September 2007
09.08.04 *SMC Report No. 112/04*	losartan (Cozaar®) *Merck Sharpe Dohme* *Hypertension with left ventricular hypertrophy.*	Accepted for use: losartan (Cozaar®) is accepted for use within NHS Scotland for the treatment of hypertensive patients with left ventricular hypertrophy. In a large international trial a losartan-based regimen reduced the risk of stroke compared with a beta-blocker-based regimen in patients with hypertension and left ventricular hypertrophy (LVH), who were without clinically evident vascular disease. There are no data on benefits relative to other antihypertensive agents. The trial data are included in the British Hypertension Society guidelines and reference should be made to these with regard to treatment choices for individual patients. An economic model indicates that a losartan-based regimen is cost effective in patients with hypertension and LVH compared with a beta-blocker-based regimen.	Added to the Formulary.
08.11.04 *SMC Report No. 131/04*	losartan (Cozaar®) *Merck, Sharpe & Dohme* *To delay the progression of renal disease and to reduce proteinuria in type 2 diabetic patients with nephropathy.*	Restricted use: losartan is accepted for restricted use within NHS Scotland to delay the progression of renal disease and to reduce proteinuria in type 2 diabetic patients with nephropathy. Losartan, for the management of renal disease in patients with hypertension and type 2 diabetes mellitus, is effective, but has not been shown to be any more effective than ACE inhibitors, which are generally less expensive products, and for which there is a strong evidence base in diabetic renal disease and other forms of cardiovascular disease. Therefore, losartan should be considered, along with other angiotensin II antagonists licensed for diabetic renal disease, as an alternative in patients unable to tolerate an ACE inhibitor.	Added to the Formulary.
11.02.08 *SMC Report No. 295/06* PRODUCT UPDATE (abbreviated submission)	losartan 100mg/hydrochlorothiazide 12.5mg tablet (Cozaar-Comp 100/12.5®) *Merck, Sharp & Dohme Ltd* *Treatment of hypertension in patients whose blood pressure is not adequately controlled on hydrochlorothiazide or losartan monotherapy.*	Accepted for use: losartan 100mg / hydrochlorothiazide 12.5mg tablet (Cozaar-Comp 100/12.5®) is accepted for use within NHS Scotland for the treatment of hypertension in patients whose blood pressure is not adequately controlled on hydrochlorothiazide or losartan monotherapy. In patients for whom this combination of antihypertensive agents is appropriate, it allows more flexible dosing than previously available combination products. This fixed dose combination is one of many options for the treatment of hypertension, including other less expensive angiotensin receptor blocker/diuretic combinations.	'Not preferred' as suitable alternatives exist. FC March 2008
07.08.06 *SMC Report No. 296/06* PRODUCT UPDATE (abbreviated submission)	losartan 100mg/hydrochlorothiazide 25mg tablets (Cozaar-Comp® 100/25) *Merck, Sharpe & Dohme Ltd* *Treatment of essential hypertension in patients whose blood pressure is not adequately controlled on hydrochlorothiazide or losartan monotherapy.*	Accepted for use: losartan 100mg/hydrochlorothiazide 25mg tablet (Cozaar-Comp® 100/25) is accepted for use within NHS Scotland for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on hydrochlorothiazide or losartan monotherapy. No increased costs are associated with this product compared with losartan (Cozaar®) 100mg alone. Compared with a previously available combination product it reduces the tablet burden when higher doses of losartan and hydrochlorothiazide are required. This fixed dose combination is one of many options for the treatment of hypertension, including other less expensive angiotensin receptor blocker/diuretic combinations.	'Not preferred' as suitable alternatives exist. FC October 2007

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09.06.08 *SMC Report No. 484/08* NON SUBMISSION	loteprednol etabonate 0.5% 5mg/ml (Lotemax 0.5% eye drops, suspension) *Bausch & Lomb GmbH* *Treatment of post-operative inflammation following ocular surgery.*	NOT RECOMMENDED: loteprednol etabonate 5mg/ml eye drops (Lotemax 0.5% eye drops, suspension) are not recommended for the treatment of post-operative inflammation following ocular surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.04.14 *SMC Report No. 952/14* Patient Access Scheme	macitentan, 10mg film-coated tablets (Opsumit®) *Actelion Pharmaceuticals Limited* *As monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension in adult patients of World Health Organisation Functional Class II to III.*	Restricted use: macitentan (Opsumit®) is accepted for restricted use within NHS Scotland as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension in adult patients of World Health Organisation Functional Class II to III. SMC restriction: to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or similar specialists. In a pivotal phase III study in patients with pulmonary arterial hypertension, macitentan significantly increased the time to a first event related to morbidity or mortality from any cause compared with placebo. The effect was maintained for up to two years. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of macitentan. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question, as per the SMC restriction. Only initiated and prescribed by specialist in the Scottish Pulmonary Vascular Unit or similar specialist. FC April 2014
13.04.04 *SMC Report No. 94/04*	macrogol 4000 (Idrolax®) *Schwarz Pharma Ltd* *Treatment of constipation in adults and children aged 8 years and above.*	NOT RECOMMENDED: macrogol 4000 (Idrolax®) is not recommended for use within NHS Scotland for the treatment of constipation in adults and children aged 8 years and above. Macrogol 4000 is as effective as lactulose, but the available evidence does not justify the additional cost of this product. The licence holder has indicated their intention to resubmit.	NOT RECOMMENDED
12.07.04 *SMC Report No. 103/04* PRODUCT UPDATE (abbreviated submission)	macrogol '3350', sodium bicarbonate, sodium chloride, potassium chloride (Movicol® Paediatric Plain) *Norgine Ltd* *Treatment of paediatric faecal impaction.*	Accepted for use: Movicol® Paediatric Plain is accepted for use in Scotland as an alternative to Movicol®-Half for the treatment of paediatric faecal impaction. The new product is a reformulation of an existing paediatric presentation of macrogol to remove flavour and sweetener, and no clinical data have been considered in drafting this recommendation.	Added to the LJF for Children as a Prescribing Note. FC April 2005
09.12.13 *SMC Report No. 837/13* RESUBMISSION	mannitol 40mg inhalation powder hard capsule (Bronchitol®) *Pharmaxis Pharmaceuticals Ltd.* *Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care.*	Restricted use: mannitol (Bronchitol®) is accepted for restricted use within NHS Scotland for the treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. SMC restriction: As an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining lung function and in whom other osmotic agents are considered unsuitable. In two phase III clinical studies in patients with CF, inhaled mannitol was superior to a control treatment (a sub-therapeutic dose of inhaled mannitol) measured by absolute change in forced expiratory volume in one second (FEV1) over 26 weeks.	**Included** on the LJF, for Specialist Initiation, for the indication in question. Suitable for shared care. FC July 2014

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.10.08 *SMC Report No. 458/08* RESUBMISSION	maraviroc, 150 mg and 300 mg tablets (Celsentri®) *Pfizer Ltd* *Treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable.*	NOT RECOMMENDED: maraviroc (Celsentri®) is not recommended for use within NHS Scotland in combination with other antiretroviral medicinal products, for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable. When added to optimised background therapy, maraviroc was associated with a significant reduction in viral load compared with addition of placebo in heavily pre-treated patients. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
07.09.09 *SMC Report No. 563/09*	mecasermin, 10mg/mL solution for injection (Increlex®) *Ipsen Limited* *For the long-term treatment of growth failure in children and adolescents with severe primary insulin-like growth factor-1 deficiency (primary IGFD).*	Accepted for use: mecasermin (Increlex®) is accepted for use within NHS Scotland for the long-term treatment of growth failure in children and adolescents with severe primary insulin-like growth factor-1 deficiency (primary IGFD). Mecasermin significantly improved mean height velocity, mean height velocity standard deviation (SD) score and mean cumulative change in height SD score for at least 6 years. Serious adverse effects including hypoglycaemia and tonsillar hypertrophy are common and long-term safety data are lacking.	Added to the Additional List. FC March 2010
09.09.13 *SMC Report No. 896/13* PRODUCT UPDATE (abbreviated submission)	medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press) *Pfizer Ltd* *For long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week).*	Accepted for use: medroxyprogesterone acetate injection (Sayana® Press) is accepted for use within NHS Scotland for long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year. In adolescents (12-18years), use of medroxyprogesterone acetate injection is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with medroxyprogesterone acetate injection during the critical period of bone accretion. Sayana® Press contains medroxyprogesterone acetate for subcutaneous injection at a similar cost to the existing deep intramuscular injection.	**Included** on the LJF for the indication in question. The LJF chapter will be reviewed. FC August 2013
11.08.08 *SMC Report No. 500/08* NON SUBMISSION	melatonin 2mg prolonged-release tablets (Circadin®) *Lundbeck Limited* *Short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.*	NOT RECOMMENDED: melatonin prolonged-release tablets (Circadin®) are not recommended for use within NHS Scotland as monotherapy for the short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
23.03.11 Multiple Technology Appraisal No. 217	memantine (Ebixa®) *Lundbeck Ltd* *Moderately severe to severe Alzheimer's disease.*	NICE (Multiple Technology Appraisal Guidance No. 217 – Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (review of NICE technology appraisal guidance 111) The review and re-appraisal of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease has resulted in a change in the NICE guidance. Specifically: · donepezil, galantamine and rivastigmine are now recommended as options for managing mild as well as moderate Alzheimer's disease, and · memantine is now recommended as an option for managing moderate Alzheimer's disease for people who cannot take AChE inhibitors, and as an option for managing severe Alzheimer's disease. SMC has previously issued advice for the following drugs and indications however, the NICE appraisal, published on 23 March 2011, has been considered by NHS Quality Improvement Scotland through its revised procedure of processing of NICE appraisals. No important differences were identified for this NICE appraisal and NHS Quality Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales therefore the NICE MTA supersedes previous SMC advice. NHS Scotland should take account of the NICE appraisal and ensure that recommended drugs or treatments are made available to meet clinical need.	Added to the Formulary as second choice. For community based patients only. FC September 2011
13.08.12 *SMC Report No. 798/12* PRODUCT UPDATE (abbreviated submission)	mercaptopurine 20mg/mL oral suspension (Xaluprine®) *Nova Laboratories Limited* *For the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children.*	Accepted for use: mercaptopurine 20mg/mL oral suspension (Xaluprine®) is accepted for use within NHS Scotland for the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children. Mercaptopurine dosing is governed by cautiously monitoring haematotoxicity. The oral suspension and tablet formulations are not bioequivalent in terms of peak plasma concentrations and therefore careful haematological monitoring of the patient is advised on switching formulations. Mercaptopurine oral suspension is more expensive than the tablet formulation.	**Included** on the Additional List for the indication in question, where an oral suspension is required. FC August 2012
11.02.08 *SMC Report No. 222/05* PRODUCT UPDATE (abbreviated submission)	mesalazine modified release tablet 800mg (Asacol®) *Procter and Gamble Pharmaceuticals UK Ltd* *Treatment of moderate acute exacerbations of ulcerative colitis up to a maximum dose of 4.8 g daily.*	Accepted for use: mesalazine 800mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the treatment of moderate acute exacerbations of ulcerative colitis up to a maximum dose of 4.8g daily. The maximum recommended dose has been increased from 2.4g daily, and at the revised dose, the 800mg strength allows halving of the pill burden compared with the 400mg formulation. There will be a pro-rata increase in cost associated with the new maximum dose but no extra costs arise from the change in formulation.	New strength of a product already in the formulary. FC January 2008
11.02.08 *SMC Report No. 223/05* PRODUCT UPDATE (abbreviated submission)	mesalazine modified release tablets 800mg (Asacol®) *Procter and Gamble Pharmaceuticals UK Ltd* *Treatment of mild acute exacerbations of ulcerative colitis.*	Accepted for use: Mesalazine 800 mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the treatment of mild acute exacerbations of ulcerative colitis. At the recommended dose of up to 2.4g daily, the 800mg strength allows halving of the pill burden compared with the 400mg formulation at no extra cost.	New strength of a product already in the formulary. FC January 2008

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.02.08 *SMC Report No. 224/05* PRODUCT UPDATE (abbreviated submission)	mesalazine modified release tablet 800mg (Asacol®) *Procter and Gamble Pharmaceuticals UK Ltd* *Maintenance of remission in ulcerative colitis and Crohn's ileo-colitis.*	Accepted for use: Mesalazine 800mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the maintenance of remission in ulcerative colitis and Crohn's ileo-colitis. At the recommended dose of up to 2.4g daily, the 800mg strength allows halving of the pill burden compared with the 400mg formulation at no extra cost.	New strength of a product already in the formulary. FC January 2008
10.03.08 *SMC Report No. 445/08* PRODUCT UPDATE (abbreviated submission)	mesalazine 1200mg gastro-resistant, prolonged release tablet (Mezavant XL®) *Shire Pharmaceuticals Limited* *Induction of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis, and for maintenance of remission.*	Accepted for use: mesalazine 1200mg gastro-resistant prolonged release tablet (Mezavant XL®) is accepted for use within NHS Scotland for the induction of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis, and for maintenance of remission. It may be used in cases where mesalazine is an appropriate choice of treatment and offers the possible advantage of once-daily administration.	Added to the Formulary as a prescribing note. FC November 2008
12.10.09 *SMC Report No. 148/04* 2nd RESUBMISSION	metformin hydrochloride prolonged release 500mg tablets (Glucophage SR®) *Merck Pharmaceuticals* *Treatment of adults with type-2 diabetes.*	Restricted use: metformin hydrochloride prolonged release tablets (Glucophage SR®) are accepted for restricted use for the treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. This new formulation appears to have similar short-term efficacy to immediate-release metformin. Evidence of improved gastrointestinal tolerability is not convincing and the prolonged-release formulation is more expensive than the immediate-release formulation. It is restricted to use in patients who are intolerant of immediate release metformin and in whom the prolonged release tablet allows the use of a dose of metformin not previously tolerated or in patients for whom a once-daily preparation offers a clinically significant benefit.	Added to the LJF as a prescribing note, for patients intolerant of metformin IR. FC December 2009
12.04.10 *SMC Report No. 610/10* PRODUCT UPDATE (abbreviated submission)	metformin 500mg and 1000mg powder for oral solution (Glucophage®) *Merck Serono Limited* *The treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control:* *• In adults, metformin may be used as monotherapy or in combination with other oral anti-diabetic agents or insulin;* *• In children, from 10 years of age and adolescents, metformin may be used as monotherapy or in combination with insulin.*	Restricted use: metformin powder for oral solution (Glucophage®) is accepted for restricted use within NHS Scotland. Licensed indication under review: the treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control: • In adults, metformin may be used as monotherapy or in combination with other oral anti-diabetic agents or insulin; • In children, from 10 years of age and adolescents, metformin may be used as monotherapy or in combination with insulin. A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure. SMC restriction: Use is restricted to patients who are unable to swallow the solid dosage formulation. There is a price premium relative to metformin immediate release tablets but a saving compared to an existing formulation of metformin oral solution.	Added to the LJF as a prescribing note. FC April 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
11.12.06 *SMC Report No. 332/06* PRODUCT UPDATE (abbreviated submission)	methotrexate injection 10mg/mL (Metoject®) pre-filled syringes 7.5mg, 10mg, 15mg, 20mg, 25mg *Medac UK* *Treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs (DMARD) is indicated.*	Accepted for use: methotrexate injection 10mg/mL (Metoject®) is accepted for use in NHS Scotland for the treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs (DMARD) is indicated. For patients in whom parenteral methotrexate is appropriate, this is the first licensed parenteral formulation for this indication.	Added to the Additional List. FC July 2009 Now available as 50mg/mL pre-filled syringes.
12.10.09 *SMC Report No. 573/09* PRODUCT UPDATE (abbreviated submission)	methotrexate injection 10mg/mL (Metoject®) pre-filled syringes 7.5mg, 10mg, 15mg, 20mg, 25mg *Medac UK* *Treatmnet of psoriasis and psoariatic arthritis.*	Accepted for use: methotrexate injection 50mg/ml (Metoject®) is accepted for use in NHS Scotland for the treatment of severe recalcitrant disabling psoriasis which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients. For patients in whom parenteral methotrexate is appropriate, this is the first licensed parenteral formulation for this indication.	Added to the Additional List. FC September 2009 Now available as 50mg/mL pre-filled syringes.
08.08.11 *SMC Report No: 724/11* PRODUCT UPDATE (abbreviated submission)	methotrexate 50mg/mL solution for injection (Metoject®) prefilled syringes 12.5mg, 17.5mg, 22.5mg, 27.5mg and 30mg *Medac GmbH* *Polyarthritic forms of severe active juvenile idiopathic arthritis, when the response to non-steroidal anti-inflammatory drugs has been inadequate.*	Accepted for use: methotrexate 50mg/mL solution for injection (Metoject®) is accepted for use within NHS Scotland. Indication under review: polyarthritic forms of severe active juvenile idiopathic arthritis, when the response to non-steroidal anti-inflammatory drugs has been inadequate. For patients in whom treatment with disease modifying drugs is indicated and parenteral administration of methotrexate is appropriate, this adds to the range of pre filled syringes available. The Scottish Medicines Consortium has previously accepted methotrexate for the treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs is indicated. Methotrexate injection is listed in the British National Formulary for Children 2010 -11 for the treatment of juvenile idiopathic arthritis.	Added to the Additional List. FC August 2011
07.04.08 *SMC Report No. 455/08*	methoxy polyethylene glycol-epoetin beta, for injection (Mircera®) *Roche* *Treatment of anaemia associated with chronic kidney disease.*	Accepted for use: methoxy polyethylene glycol-epoetin beta (Mircera®) is accepted for use within NHS Scotland for treatment of anaemia associated with chronic kidney disease. Clinical studies have demonstrated the efficacy of methoxy polyethylene glycol-epoetin beta in correcting and maintaining haemoglobin levels for up to a year in dialysis patients, when administered by either the subcutaneous or intravenous route. Non-inferiority to other erythropoiesis stimulating agents, with respect to achieving and maintaining haemoglobin levels, was demonstrated.	Added to LJF as a prescribing note. FC March 2010
10.11.03 *SMC Report No. 50/03* RESUBMISSION	methyl aminolevulinate 160mg/g cream (Metvix®) *Galderma (UK) Ltd* *Treatment of thin or non-hyperkeratotic and non-pigmented actinic keratosis on the face and scalp.*	Accepted for use: The evidence of efficacy for Metvix® for the treatment of thin or non-hyperkeratotic and non-pigmented actinic keratosis on the face and scalp is not strong. The health economic evidence is incomplete, though it suggests similar costs to the alternative treatment (cryotherapy). However, Metvix® appears to have a place for treatment of those patients when other therapies are considered less appropriate and should be delivered by a dermatologist experienced in this therapy.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
10.11.03 *SMC Report No. 51/03* RESUBMISSION	methyl aminolevulinate cream (Metvix®) *Galderma* *Treatment of basal cell carcinoma in those patients in whom standard treatment with surgery or cryotherapy is contraindicated.*	Restricted use: methyl aminolevulinate cream (Metvix®) appears to be effective for the treatment of basal cell carcinoma in those patients in whom standard treatment with surgery or cryotherapy is contraindicated. Its use should be restricted to specialist dermatologists and to superficial lesions where penetration is most effective.	Added to the Additional List. FC October 2005

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.12.08 *SMC Report No. 518/08*	methylnaltrexone 12mg in 0.6ml solution for injection (Relistor®) *Wyeth Europa Limited* *Ttreatment of opioid induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient.*	Restricted use: methylnaltrexone (Relistor®) is accepted for restricted use within NHS Scotland for treatment of opioid induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. It is restricted to use by physicians with expertise in palliative care. Methylnaltrexone has been shown to be superior to placebo in achieving bowel movement in terminally ill patients with opioid-induced constipation already receiving a stable laxative regimen.	'Not preferred' in Lothian, as suitable alternatives exist. FC September 2009
09.05.05 *SMC Report No. 99/04*	methylphenidate modified release (Equasym XL®) *Celltech* *Treatment of attention deficit/hyperactivity disorder (ADHD) as part of a comprehensive treatment programme, when remedial measures alone prove insufficient.*	Restricted use: methylphenidate modified release (Equasym XL®) is accepted for restricted use within NHS Scotland for the treatment of attention deficit/hyperactivity disorder (ADHD) as part of a comprehensive treatment programme, when remedial measures alone prove insufficient. Like other modified release methylphenidate formulations, it should be considered second line and used only in exceptional circumstances where the supervising clinician has clear evidence that administration of a midday dose is problematic or inappropriate. As for other methylphenidate preparations, initiation of treatment should be by a specialist in childhood behaviour disorders. The pharmacokinetic profile of Equasym XL® differs from that of other modified release formulations of methylphenidate. Equasym XL® would be suitable for patients who do not require therapy in the evening or could have been managed on morning and lunchtime immediate release methylphenidate.	Added to the LJF, for use in exceptionally problematic patients/circumstances only, where the supervising clinician has clear evidence that administration of a midday dose is problematic or inappropriate. Concerta® XL (methylphenidate modified release) is already included in the LJF. Equasym XL® increases the range of formulations and strengths available. Use of m/r formulations reduces flexibility of dosage which can be a disadvantage for many children and parents. FC June 2005
09.07.07 *SMC Report No. 388/07* PRODUCT UPDATE (abbreviated submission)	methylphenidate prolonged-release capsule (Medikinet XL®) *Flynn Pharma Ltd* *As part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children over 6 years of age when remedial measures alone prove insufficient.*	Restricted use: methylphenidate prolonged-release capsule (Medikinet XL®) is accepted for restricted use within NHS Scotland as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children over 6 years of age when remedial measures alone prove insufficient. Like other modified release methylphenidate formulations, it should be considered second line and used for patients requiring methylphenidate in the morning and afternoon when administration of a midday dose is problematic or inappropriate. Treatment should be under the supervision of a specialist in childhood behaviour disorders. The pharmacokinetic profile of Medikinet XL® differs from those of other modified release formulations of methylphenidate.	New formulation of a drug already included in the Formulary. FC October 2007
05.07.02 *SMC Report No. 04/02*	methylphenidate sustained release OROS formulation (Concerta® XL) *Janssen-Cilag* *Part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) when remedial measures alone prove insufficient (under specialist supervision).*	Restricted use: Treatment with methylphenidate should be part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) when remedial measures alone prove insufficient (under specialist supervision). Because of its substantially greater costs, methylphenidate OROS should be restricted to second line therapy and used only in exceptional circumstances where the supervising clinician has clear evidence of compliance problems. As for other methylphenidate preparations, initiation should be on the recommendation of a specialist in childhood behaviour disorders.	Approved for use - added to the LJF as a Prescribing Note.
08.09.08 *SMC Report No. 497/08*	micafungin 50 and 100mg powder for solution for infusion (Mycamine®) *Astellas Pharma Ltd* *Treatment of invasive candidiasis in adults, elderly, and children (including neonates).*	Restricted use: micafungin (Mycamine®) is accepted for restricted use within NHS Scotland. It is restricted to use in the treatment of invasive candidiasis in adults, elderly, and children (including neonates). Micafungin has been shown to be non-inferior to caspofungin and liposomal amphotericin B in the treatment of patients with invasive candidiasis, the majority of whom had candidaemia and were non-neutropenic. It was effective in the treatment of both C. albicans and non-albicans Candida species.	'Not preferred' as suitable alternatives exist. FC May 2009

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.09.08 *SMC Report No. 497/08*	micafungin 50 and 100mg powder for solution for infusion (Mycamine®) *Astellas Pharma Ltd* *Treatment of oesophageal candidiasis in adult, elderly, and adolescent (≥16 years of age) patients for whom intravenous therapy is appropriate.*	NOT RECOMMENDED: micafungin (Mycamine®) is not recommended for use within NHS Scotland for the treatment of oesophageal candidiasis in adult, elderly and adolescent (≥16 years of age) patients for whom intravenous therapy is appropriate. The manufacturer did not supply any economic analysis and therefore the cost effectiveness could not be assessed.	NOT RECOMMENDED
08.09.08 *SMC Report No. 497/08*	micafungin 50 and 100mg powder for solution for infusion (Mycamine®) *Astellas Pharma Ltd* *For prophylaxis of Candida infection in adults, elderly, and children (including neonates) undergoing allogeneic haematopoietic stem cell transplantation.*	NOT RECOMMENDED: micafungin (Mycamine®) is not recommended for use within NHS Scotland for prophylaxis of Candida infection in adults, elderly, and children (including neonates) undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells/µl) for 10 or more days. The manufacturer did not supply any economic analysis and therefore the cost effectiveness could not be assessed.	NOT RECOMMENDED
07.02.11 *SMC Report No. 517/08* RESUBMISSION	miconazole, 50mg muco-adhesive buccal tablets (Loramyc®) *SpePharm UK Ltd* *Treatment of oropharyngeal candidiasis in immunocompromised patients.*	NOT RECOMMENDED: miconazole muco-adhesive buccal tablets (Loramyc®) is not recommended for use within NHS Scotland. Indication under review: The treatment of oropharyngeal candidiasis (OPC) in immunocompromised patients. Miconazole muco-adhesive buccal tablets were shown to be non-inferior in the treatment of OPC to another locally-acting miconazole preparation in patients with cancer of the head and neck who had received radiotherapy, and to another locally-acting anti-fungal in HIV-positive patients. There are no data comparing miconazole buccal tablets to treatments currently used in practice in Scotland in this patient group. Overall the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
14.04.09 *SMC Report No. 542/09*	micronised progesterone, 100mg, 200mg capsules (Utrogestan®) *Ferring Pharmaceuticals Ltd* *Adjunctive use with oestrogen in post-menopausal women with an intact uterus (HRT).*	NOT RECOMMENDED: micronised progesterone (Utrogestan®) is not recommended for use within NHS Scotland for adjunctive use with oestrogen in post-menopausal women with an intact uterus (HRT). Micronised progesterone was as effective as another progestogen in protecting the endometrium from the hyperplastic changes associated with oestrogen therapy. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
09.12.13 *SMC Report No. 935/13* NON SUBMISSION	micronized progesterone (Utrogestan Vaginal®) 200 mg capsules *Marlborough Pharmaceuticals Ltd* *Supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.*	NOT RECOMMENDED: micronized progesterone (Utrogestan Vaginal®) is not recommended for use within NHS Scotland as supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.02.12 *SMC Report No. 757/12*	midazolam, 5mg/mL, oromucosal solution (Buccolam®) *ViroPharma Ltd* *Treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years).*	Accepted for use: midazolam oromucosal solution (Buccolam®) is accepted for use within NHS Scotland for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years). Midazolam given via the buccal route was considered at least non-inferior to rectally administered benzodiazepine in terminating acute prolonged seizures. The economic case was demonstrated for midazolam oromucosal solution (Buccolam®) compared to rectal diazepam.	**Not included** on the LJF because clinicians do not support the formulary inclusion. FC October 2012
08.08.11 *SMC Report No. 621/10* RESUBMISSION Patient Access Scheme	mifamurtide, 4mg powder for suspension for infusion (Mepact®) *Takeda UK and Ireland Ltd* *Treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection. It is used in combination with post-operative multi-agent chemotherapy. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis.*	Accepted for use: mifamurtide (Mepact) is accepted for use within NHS Scotland. Indication under review: in combination with post-operative multi-agent chemotherapy for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection, in children, adolescents and young adults. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis. Mifamurtide has been shown to increase overall survival compared with multi-agent chemotherapy alone in patients aged up to 30 years with newly-diagnosed resectable osteosarcoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mifamurtide. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only. FC September 2011
13.12.04 *SMC Report No. 133/04*	miglustat (Zavesca®) *Actelion* *Treatment of mild to moderate type 1 Gaucher's disease in patients for whom enzyme replacement therapy is unsuitable.*	Accepted for use: miglustat is accepted for use within NHS Scotland for the treatment of mild to moderate type 1 Gaucher disease in patients for whom enzyme replacement therapy is unsuitable. Miglustat should only be initiated by physicians experienced in the management of Gaucher's disease.	Added to the Additional List, to be prescribed and dispensed by secondary care Specialists only. FC January 2005
13.07.10 *SMC Report No. 632/10* NON SUBMISSION	miglustat (Zavesca®)100 mg hard capsules *Actelion Pharmaceuticals UK Ltd* *Treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease.*	NOT RECOMMENDED: miglustat (Zavesca®) is not recommended for use within NHSScotland for the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.05.13 *SMC Report No. 862/13*	mirabegron 25mg and 50mg prolonged-release tablets (Betmiga®) *Astellas Pharma Ltd* *For symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.*	Accepted for use: mirabegron (Betmiga®) is accepted for use within NHS Scotland for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome. Mirabegron was associated with modest treatment benefits over placebo in reducing symptoms associated with overactive bladder syndrome, including frequency and incontinence. Alternative treatments are available at a lower drug acquisition cost.	**Included** on the LJF as a prescribing note, for the indication in question. FC August 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.10.03 *SMC Report No. 66/03* ABBREVIATED SUBMISSION	mirtazapine (Zispin SolTab®) *Organon Laboratories Ltd* *New formulation of existing therapy: Treatment of depressive illness.*	Zispin SolTab® (mirtazapine) is an orodispersible tablet formulation which is less expensive than mirtazapine tablets of the same dose and is therefore a suitable alternative preparation in patients receiving this drug for the treatment of depressive illness.	Remains on the Additional List. Zispin SolTab® is a new formulation of mirtazapine very occasionally used to treat depression when first and second choice drugs are ineffective, not tolerated or contra-indicated. FC January 2004
11.12.06 *SMC Report No. 328/06*	mitotane 500mg tablets (Lysodren®) *Laboratoire HRA Pharma* *Symptomatic treatment of advanced (unresectable, metastatic or relapsed) adrenal cortical carcinoma.*	NOT RECOMMENDED: mitotane (Lysodren®) is not recommended for use within NHS Scotland for the symptomatic treatment of advanced (unresectable, metastatic or relapsed) adrenal cortical carcinoma. The effect of mitotane on non-functional adrenal cortical carcinoma is not established. Mitotane relieves the symptoms of advanced adrenal cortical carcinoma, but there is insufficient evidence to support an increase in survival. The economic case has not been demonstrated. Mitotane should be used only within the context of clinical trials.	NOT RECOMMENDED
13.03.06 *SMC Report No. 63/03* RESUBMISSION	modafinil 100mg and 200mg tablets (Provigil®) *Cephalon* *Resubmission for new indication: excessive sleepiness associated with obstructive sleep apnoea / hypopnoea syndrome.*	NOT RECOMMENDED: modafinil (Provigil®) is not recommended for use within NHS Scotland for the treatment of excessive sleepiness associated with obstructive sleep apnoea / hypopnoea syndrome. Modafinil demonstrated modest improvement in sleepiness and quality of life, the clinical significance of which is difficult to estimate. The submitted health economic case had some uncertainties and failed to demonstrate cost effectiveness.	NOT RECOMMENDED
13.06.05 *SMC Report No. 183/05*	modafinil 100mg and 200mg tablets (Provigil®) *Cephalon* *New indication: Excessive sleepiness associated with shift work sleep disorder.*	NOT RECOMMENDED: modafinil (Provigil®) is not recommended for use within NHS Scotland for the treatment of excessive sleepiness associated with moderate to severe shift work sleep disorder. Modafinil demonstrated a modest improvement in sleepiness and quality of life, the clinical significance which is difficult to estimate. The submitted health economics case does not demonstrate cost-effectiveness of the therapy.	NOT RECOMMENDED
10.11.03 *SMC Report No. 79/03*	mometasone furoate (Asmanex Twisthaler®) *Schering-Plough* *Treatment of asthma.*	Restricted use: mometasone is the fourth inhaled steroid licensed for treatment of asthma. It is available as a dry powder inhaler. It has a similar efficacy and adverse event profile to other currently available inhaled steroids. It is suitable for use as a second line agent following treatment failure on first line inhaled steroids.	'Not preferred' in the Adult Formulary as effective alternatives are available. FC November 2004 Not Preferred in the LJF for Children as effective alternatives are available. FC April 2005

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.07.07 *SMC Report No. 383/07*	montelukast 4mg and 5mg chewable tablets and 4mg granules (Singulair Paediatric®) *Merck, Sharp & Dohme Ltd* *As an alternative treatment option to low-dose inhaled corticosteroids for patients, [children 2 to 14 years of age] with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids.*	Restricted use: montelukast chewable tablet and granules (Singulair Paediatric®) is accepted for restricted use within NHS Scotland as an alternative treatment option to low-dose inhaled corticosteroids for patients, [children 2 to 14 years of age] with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids. It should be restricted to initiation by specialists in paediatric asthma care.	Already included as a prescribing note in the paediatric formulary. FC May 2009
11.07.05 *SMC Report No. 185/05*	montelukast 10mg tablets (Singulair®) *Merck, Sharp & Dohme Ltd (MSD)* *Symptomatic relief of seasonal allergic rhinitis (SAR) in adult patients in whom montelukast is indicated in asthma, as add-on oral therapy at steps 3 and 4 of the BTS/SIGN asthma guidelines.*	Restricted use: montelukast (Singulair®) is accepted for restricted use within NHS Scotland for the symptomatic relief of seasonal allergic rhinitis (SAR) in adult patients in whom montelukast is indicated in asthma, as add-on oral therapy at steps 3 and 4 of the BTS/SIGN asthma guidelines. Other more effective and cost effective treatments for SAR are available for patients in whom montelukast is not required for the treatment of asthma.	Added to the Additional List. FC March 2006
09.08.04 *SMC Report No. 111/04* ABBREVIATED SUBMISSION	montelukast paediatric 4mg granules (Singulair®) *Merck Sharpe & Dohme Ltd* *Treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as needed' short-acting beta-agonists provide inadequate clinical control of asthma.*	Accepted for use: montelukast paediatric 4mg granules (Singulair®) are accepted for use in NHS Scotland for the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as needed' short-acting beta-agonists provide inadequate clinical control of asthma. It is also accepted for the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction. This formulation is suitable for the treatment of children aged 6 months to 5 years, and the licence for montelukast has been extended to include children aged 6 months to 2 years, though the Summary of Product Characteristics adds that experience in those aged 6 to 12 months is limited. Its introduction is expected to have minimal resource implications in Scotland.	Added to the LJF for Children Formulary as a third line add-on therapy for children aged six months to two years, to be used in conjunction with bronchodilators and steroids. To be initiated by Specialists only. FC April 2005
13.10.03 *SMC Report No. 69/03*	moxifloxacin (Avelox®) *Bayer* *Treatment for community acquired pneumonia.*	Restricted use: moxifloxacin (Avelox®), a new fluoroquinolone antibiotic, should be reserved as a second-line treatment for community-acquired pneumonia in accordance with British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) guidance.	'Not preferred' in the Adult Formulary as effective alternatives are available. FC November 2003 Not Preferred in the LJF for Children as effective alternatives are available. FC April 2005
13.10.03 *SMC Report No. 70/03*	moxifloxacin (Avelox®) *Bayer* *Treatment of acute exacerbations of chronic bronchitis.*	Restricted use: moxifloxacin (Avelox®), a new fluoroquinolone antibiotic, for the treatment of acute exacerbations of chronic bronchitis, should be restricted to patients who fail to respond to conventional therapy or in whom this is contra-indicated. Its use should be in accordance with British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) guidance.	'Not preferred' in the Adult Formulary as effective alternatives are available. FC November 2003 Not Preferred in the LJF for Children as effective alternatives are available. FC April 2005

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13.12.10 *SMC Report No. 650/10*	moxifloxacin intravenous, 400mg/250mL, solution for infusion (Avelox®) *Bayer Schering* *Treatment of community acquired pneumonia (CAP).*	Restricted use: moxifloxacin intravenous (Avelox®) is accepted for restricted use within NHS Scotland. Indication under review: the treatment of community acquired pneumonia (CAP). It should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents. SMC restriction: use only on the advice of microbiologists or specialists in infectious diseases. In several studies, sequential intravenous/oral moxifloxacin has been shown to be non-inferior to a range of comparative therapies. Intravenous moxifloxacin is also licensed for the treatment of complicated skin and skin structure infections. The manufacturer's submission related only to use in CAP, therefore SMC cannot recommend its use in the treatment of skin infections.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC March 2012
07.02.05 *SMC Report No. 144/04*	mycophenolic acid (as mycophenolate sodium), 180mg and 360mg film-coated gastro-resistant tablets (Myfortic®) *Novartis Pharmaceuticals UK Limited* *Prophylaxis of acute transplant rejection in adult patients receiving allogenic renal transplants in combination with ciclosporin and corticosteroids.*	Accepted for use: mycophenolate sodium (Myfortic®) is accepted for use within NHS Scotland for the prophylaxis of acute transplant rejection in adult patients receiving allogenic renal transplants in combination with ciclosporin and corticosteroids. It is restricted to use by transplant specialists as part of an immunosuppressive regimen.	Added to the Additional List. Suitable for shared care protocol. FC March 2012
10.09.07 *SMC Report No. 329/06* RESUBMISSION	natalizumab 300mg concentrate for solution for infusion (Tysabri®) *Biogen Idec Ltd* *Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following patient groups; patients with high disease activity despite treatment with beta-interferon and in patients with rapidly evolving severe RRMS.*	Accepted for use: natalizumab (Tysabri®) is accepted for restricted use within NHS Scotland as single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) only in patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year and with one or more gadolinium-enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load compared with a previous MRI. In a post-hoc sub-group analysis of the pivotal trial, which included patients with rapidly evolving severe RRMS, it was associated with a significant reduction in the annualised relapse rate and the probability of sustained progression of disability over two years compared with placebo.	Added to the formulary for Specialist Use only by a Consultant Neurologist. FC January 2008
09.06.14 *SMC Report No. 979/14* NON SUBMISSION	natalizumab (Tysabri®) 300 mg concentrate for solution for infusion *Biogen Idec Ltd* *Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate.*	NOT RECOMMENDED: natalizumab (Tysabri®) is not recommended for use within NHS Scotland as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate. SMC has previously not recommended natalizumab for use in patients with high disease activity despite treatment with beta-interferon. The marketing authorisation has now been extended to include use in patients with high disease activity despite treatment with glatiramer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland. SMC has previously accepted natalizumab (Tysabri®) for restricted use as a single disease modifying therapy in highly active RRMS in patients with rapidly evolving severe RRMS and this advice remains in place.	NOT RECOMMENDED

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13.08.07 *SMC Report No. 214/05* RESUBMISSION	nebivolol tablets 5mg (Nebilet®) *Menarini Pharmaceuticals UK SRL* *Treatment of stable mild and moderate chronic heart failure (CHF) in addition to standard therapies in elderly patients ≥70 years.*	Accepted for use: nebivolol (Nebilet®) is accepted for use within NHS Scotland for the treatment of stable mild and moderate chronic heart failure (CHF) in addition to standard therapies in elderly patients ≥70 years. Compared to placebo, nebivolol, added to standard therapy, was associated with improved left ventricular function and a reduction in a composite endpoint combining all cause mortality and cardiovascular hospitalisation rates in elderly patients with chronic heart failure. There are no direct comparisons with other beta-blockers that are available at a lower acquisition cost.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010
07.04.08 *SMC Report No. 454/08*	nelarabine, 5mg/ml solution for infusion (Atriance®) *GlaxoSmithKline UK* *Treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to, or has relapsed following, treatment with at least two chemotherapy regimens.*	Restricted use: nelarabine (Atriance®) is accepted for restricted use within NHS Scotland for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to, or has relapsed following, treatment with at least two chemotherapy regimens. It is restricted to patients in whom nelarabine is being used as a treatment to bridge to allogeneic stem cell transplant and restricted to use by specialists in haemato-oncology. It is not cost-effective when used for palliation.	Added to the Additional List, Specialist use only. FC November 2009
09.11.09 *SMC Report No. 588/09* NON SUBMISSION	nepafenac (Nevanac ®) *Alcon Laboratories* *For prevention and treatment of postoperative pain and inflammation associated with cataract surgery.*	NOT RECOMMENDED: in the absence of a submission from the holder of the marketing authorisation. nepafenac (Nevanac®) is not recommended for use within NHSScotland for prevention and treatment of postoperative pain and inflammation associated with cataract surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.11.12 *SMC Report No. 813/12*	nepafenac 1mg/mL eye drops, suspension (Nevanac®) *Alcon Laboratories (UK) Ltd* *Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.*	Accepted for use: nepafenac (Nevanac®) is accepted for use within NHS Scotland for reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. In the pivotal study which included diabetic patients who had undergone cataract surgery, nepafenac eye drops significantly reduced the incidence of macular oedema compared to vehicle.	**Included** on the LJF as a prescribing note, for Specialist Initiation only, for the indication in question. FC May 2014
13.02.06 *SMC Report No. 93/04* RESUBMISSION	nicotinic acid 375mg, 500mg, 750mg, 1000mg modified release tablet (Niaspan®) *Merck* *Treatment of dyslipidaemia.*	NOT RECOMMENDED: nicotinic acid modified release tablet (Niaspan®) is not recommended for use within NHS Scotland for the treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia, characterised by elevated levels of low-density-lipoprotein (LDL)-cholesterol and triglycerides and low high-density-lipoprotein (HDL)-cholesterol, and in patients with primary hypercholesterolaemia, either in combination with a HMG-CoA reductase inhibitor (statin), when the cholesterol lowering effect of HMG-CoA reductase inhibitor monotherapy is inadequate or as monotherapy in patients who do not tolerate HMG-CoA reductase inhibitors. Niaspan® increases HDL cholesterol, reduces triglycerides and to a lesser extent reduces LDL cholesterol. There is no clinical trial evidence that Niaspan® reduces the occurrence of long-term cardiovascular events in patients who have acceptable LDL cholesterol and triglycerides and low HDL (isolated low HDL). The economic case has not been demonstrated.	NOT RECOMMENDED

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10.05.10 *SMC Report No: 614/10*	extended release nicotinic acid/laropiprant, 1000mg/20mg modified release tablets (Tredaptive®) *Merck Sharp & Dohme Ltd* *Treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDL-cholesterol) and in patients with primary hypercholesterolaemia (heterozygous familial and non familial). It can be used as monotherapy only in patients in whom HMG-CoA reductase inhibitors are considered inappropriate or not tolerated.*	Restricted use: extended release nicotinic acid/laropiprant (Tredaptive®) is accepted for restricted use within NHSScotland. Licensed indication under review: the treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDL-cholesterol) and in patients with primary hypercholesterolaemia (heterozygous familial and non familial) as monotherapy in patients in whom HMG-CoA reductase inhibitors are considered inappropriate or not tolerated. Diet and other non-pharmacological treatments (e.g. exercise, weight reduction) should be continued during therapy with extended release nicotinic acid/laropiprant. SMC restriction: as monotherapy for the treatment of dyslipidaemia in patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDLcholesterol) in patients in whom HMG-CoA reductase inhibitors are considered inappropriate or not tolerated. In patients, who may or may not have also been taking an HMG-CoA reductase inhibitor, extended release nicotinic acid/laropiprant reduced LDL-cholesterol versus placebo across weeks 12 to 24 and reduced flushing versus extended release nicotinic acid alone during the initiation phase. Nicotinic acid/laropiprant is also licensed for use in combination with HMG-CoA reductase inhibitors (statins) when the cholesterol lowering effect of HMG-CoA reductase inhibitor monotherapy is inadequate. The manufacturer's submission related only to the use of nicotinic acid/laropiprant as monotherapy. SMC cannot recommend the use of nicotinic acid/laropiprant in combination with HMGCoA reductase inhibitors.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2011 Product no longer available. Withdrawn from the market in January 2013.
07.10.13 *SMC Report No. 917/13*	nalmefene 18mg film-coated tablets (Selincro®) *Lundbeck Limited* *The reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification.*	Accepted for use: nalmefene 18mg film-coated tablets (Selincro®) are accepted for use within NHS Scotland for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment. In a post hoc analysis of two pivotal phase III studies representing the licensed population, nalmefene was shown to significantly reduce alcohol intake compared with placebo, measured as a reduction in heavy drinking days and total alcohol consumption over a six month period.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC November 2013

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07.11.11 *SMC Report No. 734/11*	naproxen/esomeprazole 500mg/20mg modified release tablets (Vimovo®) *AstraZeneca UK* *The symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS), in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient.*	NOT RECOMMENDED: naproxen 500mg/esomeprazole 20mg (Vimovo®) is not recommended for use within NHS Scotland the symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS), in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient. Studies have demonstrated that combined naproxen/esomeprazole was associated with a lower incidence of endoscopic gastric ulcers than NSAID alone and similar improvements in pain and functioning compared to a cyclo-oxygenase-2 selective inhibitor. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
13.02.12 *SMC Report No. 760/12* PRODUCT UPDATE (abbreviated submission)	nevirapine 50mg, 100mg, 400mg prolonged release tablets (Viramune prolonged release tablets®) *Boehringer Ingelheim Ltd* *In combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children three years and above and able to swallow tablets*.	Accepted for use: nevirapine prolonged release tablets (Viramune®) are accepted for use in NHS Scotland in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children three years and above and able to swallow tablets. Once daily dosing with the nevirapine prolonged release formulation demonstrated non-inferior efficacy to the immediate release nevirapine formulation at 48 weeks in both treatment-naïve and treatment-experienced patients. When combined with other HIV therapies the once daily formulation may provide a more convenient dosing schedule for patients.	Added to the Additional List, for Specialist Use only. FC March 2012
09.06.08 *SMC Report No. 440/08* *Superseded by MTA 241 Januray 20120*	nilotinib, 200mg capsules (Tasigna®) *Novartis Pharmaceuticals UK Ltd* *For treatment of chronic phase Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. It should be restricted to use in patients who are in the chronic phase of the disease.*	Restricted use: nilotinib (Tasigna®) is accepted for restricted use within NHS Scotland for treatment of chronic phase Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. It should be restricted to use in patients who are in the chronic phase of the disease. The manufacturer has not made a submission for use in the accelerated phase. As a result we cannot recommend its use within NHSScotland. MTA 241 Nilotinib is recommended for the treatment of chronic or accelerated phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in adults: whose CML is resistant to treatment with standard-dose imatinib or who have imatinib intolerance and if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme.	Added to the Additional List, for Specialist Use only. FC March 2009 MTA 241 supersedes SMC advice , FC decision is still valid

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08.08.11 *SMC Report No. 709/11* Patient Access Scheme	nilotinib 150mg hard capsules (Tasigna®) *Novartis Pharmaceuticals UK Ltd* *Treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase.*	Accepted for use: nilotinib 150mg hard capsules (Tasigna®) is accepted for use within NHS Scotland. Indication under review: for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase. First-line treatment with nilotinib in newly diagnosed patients has resulted in significantly higher molecular and cytogenetic response rates compared to the standard tyrosine kinase inhibitor. Further longer term follow-up data are needed to confirm the duration of this response and assess the impact on disease progression and overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nilotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only. FC November 2011
08.07.13 *SMC Report No. 898/13* NON SUBMISSION	nomegestrol acetate/estradiol (Zoely®) 2.5 mg/1.5 mg film-coated tablets Merck Sharp & Dohme Limited Oral contraception.	NOT RECOMMENDED: nomegestrol acetate/estradiol (Zoely®) is not recommended for use within NHS Scotland as oral contraception. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.09.03 *SMC Report No. 48/03*	norelgestromin, ethinylestradiol patch (Evra®) *Janssen-Cilag* *Female contraception.*	Restricted use: norelgestromin / ethinylestradiol (Evra®) patches have efficacy and an adverse-effect profile similar to combined oral contraceptives (COCs). There is some evidence of improved overall compliance with this preparation compared with COCs. It is more expensive than these oral contraceptives. Nevertheless, it is concluded that this preparation may be of benefit in the group of women who have demonstrated, or are deemed to be at, substantial risk of poor compliance with COCs. Use of Evra®should be restricted to this group of people.	Approved for use - added to the Additional List. Evra® is a contraceptive patch. It is more expensive than COCs and use should be restricted to patients who have poor compliance with COCs. FC November 2003
09.09.13 *SMC Report No. 892/13*	ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®) *ThromboGenics NV* *In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns.*	NOT RECOMMENDED: ocriplasmin (Jetrea®) is not recommended for use within NHS Scotland in adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. In two randomised, controlled double-masked studies, significantly more patients treated with ocriplasmin than placebo achieved resolution of vitreomacular traction which may correlate with improved visual acuity. The submitting company did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED
09.08.04 *SMC Report No. 117/04* PRODUCT UPDATE (abbreviated submission)	oestradiol (Estradot®) range of transdermal patches *Novartis Pharmaceuticals UK Ltd* *Hormone replacement therapy.*	Accepted for use: The Estradot® range of transdermal hormone replacement oestradiol patches is accepted for use in Scotland. In cases where transdermal administration is appropriate, its adhesive technology offers a small patch size at the lower end of the cost range for transdermal patches.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007

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09.08.10 *SMC Report No. 626/10*	ofatumumab, 100mg concentrate for solution for infusion (Arzerra®) *GlaxoSmithKline* *Treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and alemtuzumab.*	NOT RECOMMENDED: ofatumumab (Arzerra®) is not recommended for use within NHS Scotland. Indication under review: the treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and alemtuzumab. Interim analysis of a non-randomised, single-arm small study in a subgroup of patients refractory to fludarabine and alemtuzumab found that ofatumumab produced a response rate of 58%. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and in addition the manufacturer did not present a sufficiently robust economic analysis.	NOT RECOMMENDED
06.06.03 *SMC Report No.* 44/03	olanzapine (Zyprexa®) *Eli Lilly and Co Ltd* *Oral: Treatment of moderate to severe manic episode* *Intramuscular: Rapid control of agitation and disturbed behaviours in patients with schizophrenia, or manic episodes when oral therapy is not appropriate.*	Restricted use: olanzapine is the first atypical antipsychotic to be licensed for the treatment of acute mania and is at least as effective as comparator treatments. It was associated with fewer extrapyramidal side effects than haloperidol and was similar to placebo in the rate of Parkinson-like effects. The management of mania is complex due to the variable presentation of the condition, the wide range of treatment options and a lack of clear guidance on their optimum use. The use of olanzapine in the treatment of acute mania should be restricted to patients under the overall supervision of clinicians experienced in managing this complex disorder.	Approved for use - added to the Additional List, for Specialist Use only. FC September 2003
10.05.04 *SMC Report No. 98/04*	olanzapine (Zyprexa®) *Eli Lilly & Company Ltd* *Prevention of recurrence in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.*	Accepted for use: olanzapine (Zyprexa®) is accepted for use within NHS Scotland for the prevention of recurrence in patients with bipolar disorder whose manic episode has responded to olanzapine treatment. Olanzapine has been shown to be significantly superior to placebo in delaying symptomatic relapse of mania or depression and of mania alone. Apart from weight gain, somnolence and treatment-emergent depression, most significant differences between olanzapine and active competitors favoured olanzapine.	Added to the Additional List. To be initiated in secondary care for the prevention of recurrence. FC November 2004
12.07.04 *SMC Report No. 106/04*	olanzapine (Zyprexa®) 10mg powder for solution for injection *Eli Lilly & Co* *Intramuscular use for the control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate.*	Accepted for use: olanzapine for intramuscular use is accepted for use within NHS Scotland for the control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. Intramuscular olanzapine has been shown to be at least as clinically and cost effective as haloperidol or lorazepam in treating agitation and other symptoms associated with acute schizophrenia and bipolar disorder. Both the clinical and the economic case are limited by the entry criteria for trials, which effectively restricted entry to moderately agitated patients and excluded those who were severely agitated. However, the difficulties in conducting research in this clinical situation are recognised.	Added to the Additional List, for use in specified circumstances and by Specialists only. FC October 2005
09.08.10 *SMC Report No. 624/10*	olanzapine 210mg, 300mg, 405mg powder and solvent for prolonged release suspension for injection (ZypAdhera®) *Eli Lilly and Company Limited* *Maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine.*	NOT RECOMMENDED: olanzapine long acting injection (ZypAdhera®) is not recommended for use within NHS Scotland. Indication under review: Maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine. The pivotal study showed comparable efficacy of olanzapine long-acting injection to oral olanzapine in preventing relapse in stabilised patients over 24 weeks. Supervision requirements in relation to the risk of post injection syndrome may limit the benefit of decreased frequency of administration. The manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED

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10.11.03 *SMC Report No. 78/03*	olmesartan medoxomil (Olmetec®) *Sankyo Pharma UK Ltd* *Treatment of hypertension.*	Restricted use: olmesartan has been shown to be at least as effective as other angiotensin-II receptor antagonists (ARAs) for the treatment of hypertension. It may be considered for use, along with other ARAs, as an alternative in patients unable to tolerate an ACE inhibitor.	'Not preferred' as suitable alternatives exist. FC November 2003
08.05.06 *SMC Report No. 225/05* PRODUCT UPDATE (abbreviated submission)	olmesartan/hydrochlorothiazide, 20mg/12.5mg or 20mg/25mg tablets (Olmetec Plus®) *Sankyo Pharma UK Ltd* *Treatment of hypertension as an alternative in patients unable to tolerate an ACE inhibitor, whose blood pressure is not adequately controlled by olmesartan 20mg monotherapy and for whom the addition of a thiazide diuretic is an appropriate next step.*	Restricted use: olmesartan/hydrochlorothiazide (Olmetec Plus®) tablet is accepted for restricted use in NHS Scotland for the treatment of hypertension as an alternative in patients unable to tolerate an ACE inhibitor, whose blood pressure is not adequately controlled by olmesartan 20mg monotherapy and for whom the addition of a thiazide diuretic is an appropriate next step. There is no additional cost compared to administration of olmesartan alone. The combination is competitively priced compared with other combinations of angiotensin II antagonists and thiazide diuretics. Angiotensin II receptor antagonists are an alternative to angiotensin converting enzyme (ACE) inhibitors where the latter are not tolerated. This fixed dose combination is one of a number of options for the treatment of hypertension, many of which are less expensive.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
12.10.09 *SMC Report No. 574/09* PRODUCT UPDATE (abbreviated submission)	olmesartan medoxomil / amlodipine as besilate tablet 20mg/5mg, 40mg/5mg, 40mg/10mg (Sevikar®) *Daiichi Sankyo UK Ltd* *Essential hypertension in patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipipine monotherapy.*	Accepted for use: olmesartan medoxomil/amlodipine as besilate (Sevikar®) is accepted for use in NHS Scotland for treatment of essential hypertension in patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy. In patients for whom concomitant use of these medicines is appropriate it allows administration of a single tablet at a lower or modestly increased cost compared to the individual components (depending on dose). Angiotensin receptor blockers are an alternative to ACE inhibitors where these are not tolerated. This fixed dose combination is one of many options for the treatment of hypertension, many of which are less expensive.	'Not preferred' in Lothian, as suitable alternatives exist. FC September 2009
10.10.11 *SMC Report No. 706/11* PRODUCT UPDATE (abbreviated submission	olmesartan medoxomil/amlodipine besilate/hydrochlorothiazide 20mg/5mg/12.5mg, 40mg/5mg/12.5mg, 40mg/10mg/12.5mg, 40mg/5mg/25mg, 40mg/10mg/25 mg film-coated tablets (Sevikar HCT®) *Daiichi Sankyo UK Ltd* *As substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine, and hydrochlorothiazide taken as a dual component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single formulation (hydrochlorothiazide or amlodipine).*	Accepted for use: olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT®) is accepted for use within NHS Scotland as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine, and hydrochlorothiazide taken as a dual component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single formulation (hydrochlorothiazide or amlodipine). In a phase III randomised four-arm study of patients with moderate to severe hypertension Sevikar HCT was superior to three dual combination therapies for the the primary endpoint, change in diastolic pressure. In patients for whom concomitant use of these medicines is appropriate it allows administration of a single tablet at a lower or modestly increased cost (depending on dose) compared to another dual combination product plus single component. Angiotensin receptor blockers are an alternative to ACE inhibitors where these are not tolerated. These fixed dose combinations are among many options for the treatment of hypertension, many of which are less expensive.	Not preferred in Lothian as suitable alternatives exist. FC September 2011

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.12.12 *SMC Report No. 823/12* PRODUCT UPDATE (abbreviated submission)	olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT®) *Daiichi Sankyo UK Ltd* *In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.*	Accepted for use: olmesartan medoxomil, amlodipine besilate and hydrochlorothiazide (Sevikar HCT®) is accepted for use in NHS Scotland in adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation. Two double-blind randomised studies of triple versus dual therapy demonstrated significantly better outcomes for patients in the triple therapy group in terms of the proportion of patients reaching target blood pressure and reduction in mean systolic and diastolic blood pressure. In patients for whom concomitant use of these medicines is appropriate it allows administration of a single tablet at a lower cost compared to a dual combination product plus single component. Angiotensin receptor blockers are an alternative to angiotensin-converting-enzyme (ACE) inhibitors where these are not tolerated. These fixed dose combinations are among many options for the treatment of hypertension, many of which are less expensive.	**Not included** in the LJF because the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question that are already available on the formulary. FC December 2012
09.01.06 *SMC Report No. 59/03* RESUBMISSION	olopatadine 1mg/ml eye drops, solution (Opatanol®) *Alcon Laboratories (UK) Ltd* *Treatment of ocular signs and symptoms of seasonal allergic conjunctivitis*	Accepted for use: olopatadine eye drops (Opatanol®) are accepted for use within NHS Scotland for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis. Olopatadine is a new, locally applied antihistamine and anti-allergen. It appears to have similar efficacy to other ocular preparations for seasonal allergic conjunctivitis and a lower price than some competitors, suggesting that it is cost effective compared to these higher-priced products.	Added to the Additional List. FC March 2007
08.10.07 *SMC Report No. 259/06* RESUBMISSION	omalizumab 150mg powder and solvent for injection (Xolair®) *Novartis Pharmaceuticals UK Ltd.* *Add-on therapy to improve asthma control in adult and adolescent patients (12 years of age and above) with severe persistent allergic asthma*	Restricted use: omalizumab (Xolair®) is accepted for restricted use within NHS Scotland as add-on therapy to improve asthma control in adult and adolescent patients (12 years of age and above) with severe persistent allergic asthma. It is restricted to initiation and monitoring by hospital physicians experienced in the diagnosis and treatment of severe persistent asthma. It is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control.	Added to the Additional List, for Specialist Use only. FC October 2008
12.04.10 *SMC Report No. 611/10* PRODUCT UPDATE (abbreviated submission)	omalizumab 150 mg powder and solvent for solution for injection (Xolair®) *Novartis Pharmaceuticals UK Ltd.* *Add-on therapy to improve asthma control in children (6 to <12 years of age) with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Omalizumab treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma.*	Restricted use: omalizumab (Xolair®) is accepted for restricted use within NHS Scotland. Licensed indication under review: add-on therapy to improve asthma control in children (6 to <12 years of age) with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Omalizumab treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma. SMC restriction: Use is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control. The Scottish Medicines Consortium has previously accepted this product for restricted use in adults and adolescents (12 years of age and above). Omalizumab is listed in the British National Formulary for Children for the prophylaxis of allergic asthma.	Added to the Additional List, for Specialist Use only. FC April 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.06.11 *SMC Report No 708/11* PRODUCT UPDATE (abbreviated submission	omalizumab (Xolair®) 75mg, 150mg solution for injection as prefilled syringe Novartis Pharmaceuticals UK Ltd *Omalizumab is indicated in adults, adolescents (12 years of age and older) and children (6 to <12 years of age) with convincing IgE (immunoglobulin E) mediated asthma.*	Accepted for use: omalizumab 75mg, 150mg (Xolair®) solution for injection is accepted for restricted use within NHS Scotland. SMC restriction: Use is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control. SMC has previously accepted omalizumab (Xolair®) 150mg powder and solvent for injection for restricted use in adults, adolescents and children. This submission is for a new solution for injection formulation that will replace the existing formulation. The 150mg solution for injection formulation is bioequivalent to the 150mg powder and solvent for injection formulation and costs the same. The new 75mg strength is half the cost of the 150mg injection and should eliminate wastage that occurred previously with certain doses.	Added to the Additional List, for Specialist Use only, for Children FC May 2011
24.03.13 *NICE Technology Appriasal No 278* *Supersedes SMC Report No. 708/11* Patient Access Scheme	omalizumab (Xolair®) 75mg, 150mg solution for injection as prefilled syringe *Novartis Pharmaceuticals UK Ltd.* *Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older.*	Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older: •who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), and •only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme. SMC previously issued advice recommending restricted use in patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control. This NICE TA extends the indication for use of omalizumab. SMC has previously accepted omalizumab (Xolair®) 150mg powder and solvent for injection for restricted use in adults, adolescents and children. SMC report No 708/11 is for a new solution for injection formulation that will replace the existing formulation.	**Included** on the Additional List, for Specialist Use only for the indication in question, for Adults FC August 2013
08.11.02 *SMC Report No. 15/02*	90% omega-3-acid ethyl esters (Omacor®) *Solvay Healthcare Ltd* *Secondary prevention after MI.*	Accepted for use: 90% omega-3-acid ethyl esters (Omacor®) is acceptable for general use within NHS Scotland as an additional treatment for the secondary prevention of myocardial infarction. Whilst cost effectiveness appears to be within generally acceptable limits, NHS Boards will recognise that there are now a number of established interventions for this indication. The priority given to this agent needs to be considered alongside the implementation of other effective approaches to secondary prevention of cardiovascular disease, always keeping in mind alternative dietary methods of obtaining fish oil supplementation.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. FC July 2014
08.11.02 *SMC Report No. 16/02*	90% omega-3-acid ethyl esters (Omacor®) *Solvay Healthcare Ltd* *Treatment of hypertriglyceridaemia.*	NOT RECOMMENDED: 90% omega-3-acid ethyl esters (Omacor®) is not recommended for use within the NHS in Scotland for the treatment of hypertriglyceridaemia. This is based on the lack of long-term data to indicate that reductions in triglyceride levels provide real benefit in terms of reducing cardiovascular events, on a lack of evidence of increased patient acceptability of the product, and lack of a pharmacoeconomic case for the drug.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
11.11.13 *SMC Report No 912/13* PRODUCT UPDATE (abbreviated submission)	ondansetron 4mg, 8mg orodispersible films (Setofilm®) *Norgine* *In adults:* • *Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy.* • *Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy.* • *Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy.* • *Prophylaxis and treatment of post-operative nausea and vomiting (PONV).* *In paediatric populations:* • *Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months.* • *Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥4 years.*	Restricted use: ondansetron orodispersible films (Setofilm®) are accepted for restricted use within NHS Scotland for the use: In adults: • Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy. • Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy. • Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV). In paediatric populations: • Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥4 years. SMC restriction: ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing. Generic preparations of ondansetron are available at a lower cost than the proprietary products.	**Included** on the Additional List, for the indication in question. FC November 2013
07.11.05 *SMC Report No. 211/05*	oxaliplatin 50mg, 100mg powder for intravenous infusion (Eloxatin®) *Sanofi-aventis* *New indication: Adjuvant treatment of stage III (Dukes' C) colon cancer.*	Accepted for use: oxaliplatin (Eloxatin®) is accepted for use within NHS Scotland, in combination with fluorouracil and folinic acid, for the adjuvant treatment of stage III (Dukes' C) colon cancer after complete resection of the primary tumour. Addition of oxaliplatin to a standard regimen of fluorouracil and folinic acid increased disease-free survival in patients who had undergone complete resection of stage III (Dukes' C) colon cancer. An economic evaluation demonstrated that this is a cost effective treatment option for these patients. Treatment with oxaliplatin (Eloxatin®) should be under the supervision of an oncologist.	Added to the Additional List, for Specialist Use only. FC November 2005
08.08.05 *SMC Report No. 190/05*	oxybutynin 3.9mg/24h transdermal patch (Kentera®) *UCB Pharma Ltd* *Treatment of urge incontinence and/or increased urinary frequency and urgency in patients with unstable bladder, restricted to patients who derive clinical benefit from oral oxybutynin but who experience intolerable anticholinergic side effects.*	Restricted use: oxybutynin transdermal patch (Kentera®) is accepted for restricted use within NHS Scotland for the treatment of urge incontinence and/or increased urinary frequency and urgency in patients with unstable bladder, restricted to patients who derive clinical benefit from oral oxybutynin but who experience intolerable anticholinergic side effects. It should be used in conjunction with non-pharmacological measures, including pelvic floor muscle exercises and bladder retraining. Transdermal oxybutynin appears to have similar efficacy to oral antimuscarinics and a lower rate of anticholinergic adverse events. However, patients have the additional effect of application site reactions, which in some patients lead to treatment discontinuation. Transdermal oxybutynin has a lower total cost than oral tolterodine, but a higher total cost than oral oxybutynin.	Added to the Formulary as a Prescribing Note, for patients who derive clinical benefit but suffer intolerable anticholinergic side effects from oral oxybutynin. FC November 2005

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.10.04 *SMC Report No. 125/04*	oxycodone (OxyNorm®) *Napp Pharmaceuticals* *Treatment of moderate to severe pain in patients with cancer.*	Restricted use: oxycodone (OxyNorm®) injection is accepted for restricted use within NHS Scotland only for the treatment of moderate to severe pain in patients with cancer. Use of this drug should be restricted to patients who have difficulty in tolerating morphine or diamorphine therapy. Limited data indicate that it provides analgesia similar to parenteral morphine at similar doses. However, there are no comparative data with diamorphine, the opioid recommended by Scottish Intercollegiate Guidelines Network (SIGN) for patients with cancer who require parenteral opioids. Oxycodone is more expensive than diamorphine and the economic case for this product replacing the other products has not been clearly demonstrated. Other indications for this medicine, treatment of moderate to severe post-operative pain and severe pain requiring the use of strong opioid, have yet to be considered by the Scottish Medicines Consortium. Advice on these indications will be made after the relevant submissions have been made by the licence holder.	Added to the Formulary for palliative care. To be initiated by Specialists in patients unable to tolerate morphine or diamorphine therapy. FC November 2004
08.05.06 *SMC Report No. 266/06* NON SUBMISSION	oxycodone (OxyNorm®) injection *Napp Pharmaceuticals Limited* *Treatment of post-operative pain.*	NOT RECOMMENDED: oxycodone (OxyNorm®) injection is not recommended for use within NHSScotland for the treatment of post-operative pain. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this formulation. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.09.05 *SMC Report No. 197/05*	oxycodone prolonged release tablets 5, 10, 20, 40 and 80mg (OxyContin®) *Napp Pharmaceuticals Limited* *New indication: Treatment of severe pain requiring the use of a strong opioid.*	Restricted use: oxycodone prolonged release (OxyContin®) is accepted for restricted use within NHS Scotland for the treatment of severe non-malignant pain requiring a strong opioid analgesic. Oxycodone prolonged release is restricted to use in patients in whom controlled release morphine sulphate is ineffective or not tolerated.	Added to the Formulary as a Prescribing Note. To be initiated on Specialist advice for patients with severe non-malignant pain in whom controlled release morphine sulphate is ineffective or not tolerated. FC January 2006
09.03.09 *SMC Report No. 541/09*	oxycodone/naloxone 10mg/5mg and 20mg/10mg prolonged release tablets (Targinact®) *Napp Pharmaceuticals Ltd* *Treatment of severe pain which can be adequately managed only with opioid analgesics.*	NOT RECOMMENDED: oxycodone/naloxone prolonged release tablets (Targinact®) are not recommended for use within NHS Scotland for the treatment of severe pain which can be adequately managed only with opioid analgesics. The addition of naloxone to oxycodone did not impair analgesia and improved bowel function when patients were not receiving regular laxative therapy. However the clinical benefit in patients receiving regular laxative therapy is uncertain and the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
08.11.10 *SMC Report No. 648/10*	oxycodone hydrochloride 50mg/ml solution for injection or infusion (OxyNorm®) *Napp Pharmaceuticals Limited* *Treatment of moderate to severe pain in patients with cancer.*	Restricted use: oxycodone hydrochloride 50mg/ml injection (OxyNorm®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of moderate to severe pain in patients with cancer SMC restriction: patients who have difficulty in tolerating morphine or diamorphine therapy and who require a high dose of oxycodone delivered via syringe pump which necessitates the daily preparation of an additional syringe pump if oxycodone 10mg/mL is used. No new clinical or pharmacokinetic evidence has been presented for this higher strength formulation. Comparative evidence of analgesia achieved with parenteral administration is extrapolated from the lower strength 10mg/mL oxycodone formulation compared with morphine 10mg/mL. The economic case was made only for patients in a hospice or community setting who require a high dose of oxycodone which necessitates the daily preparation of an additional syringe pump. Care should be taken to minimise any risk of administration error with the introduction of this increased strength formulation. Oxycodone 50mg/mL is also licensed for the treatment of moderate to severe post-operative pain and severe pain requiring the use of strong opioid. The manufacturer's submission related only to use in moderate to severe pain in patients with cancer therefore SMC cannot recommend the use of oxycodone 50mg/mL injection in the treatment of non-cancer pain.	'Not preferred' in Lothian as suitable alternatives exist. FC August 2011
12.04.10 *SMC Report No. 556/09*	paclitaxel (Abraxane®) *Abraxis BioScience Limited* *Treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated.*	Restricted use: paclitaxel albumin (Abraxane®) is accepted for restricted use within NHS Scotland. Licensed indication under review: the treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated. SMC restriction: Use is restricted to patients who would otherwise receive docetaxel or 3-weekly solvent-based paclitaxel as second-line treatment for metastatic breast cancer. In one study the overall response rate for paclitaxel albumin was significantly superior to solvent-based paclitaxel in a subgroup analysis of patients who had previously received one or more lines of therapy for metastatic disease. The health economic case was only demonstrated for a subset of the licensed indication which is the basis for the SMC restriction. Note that paclitaxel albumin may have substantially different pharmacological properties compared to other formulations of paclitaxel and is licensed for use in a 3-weekly dosage schedule.	Added to the Additional List for Specialist Use only. For use where docetaxel or solvent-based paclitaxel would otherwise be given. FC September 2010
09.06.14 *SMC Report No. 968/14*	paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®) *Celgene Ltd.* *In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.*	NOT RECOMMENDED: paclitaxel albumin (Abraxane®) is not recommended for use within NHS Scotland in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. In a randomised, phase III, open-label study paclitaxel albumin plus gemcitabine treatment improved median overall survival by 1.8 months compared with gemcitabine alone. The submitting company's justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
08.05.06 *SMC Report No. 272/06* NON SUBMISSION	palifermin (Kepivance®) *Amgen Ltd* *Oral mucositis in bone marrow transplantation.*	NOT RECOMMENDED: palifermin (Kepivance®) is not recommended for use within NHSScotland for the treatment of oral mucositis in bone marrow transplantation. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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07.04.08 *SMC Report No. 453/08*	paliperidone 3, 6 and 9mg prolonged release tablets (Invega®) *Janssen-Cilag* *Treatment of schizophrenia*	NOT RECOMMENDED: paliperidone (Invega®) is not recommended for use within NHS Scotland for the treatment of schizophrenia. Paliperidone has been shown to be superior to placebo in reducing symptoms of schizophrenia. However, there are limited statistical comparative data versus other atypical antipsychotics. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
11.04.11 *SMC Report No; 702/11* NON SUBMISSION	paliperidone 1.5mg, 3mg, 6mg, 9mg, 12mg prolonged release tablets (Invega ®) *Janssen-Cilag Ltd* *Treatment of psychotic or manic symptoms of schizoaffective disorder.*	NOT RECOMMENDED: paliperidone (Invega®) is not recommended for use within NHS Scotland. Indication under review: For the treatment of psychotic or manic symptoms of schizoaffective disorder. Effect on depressive symptoms has not been demonstrated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.11.11 *SMC Report No. 713/11* RESUBMISSION	paliperidone palmitate 50mg, 75mg, 100mg and 150mg prolonged release suspension for injection (Xeplion) *Janssen-Cilag Ltd* *Maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.*	Accepted for use: paliperidone palmitate prolonged release suspension for injection (Xeplion) is accepted for use within NHS Scotland. Indication under review: maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed. Paliperidone prolonged release suspension for injection was non-inferior to another atypical antipsychotic depot injection in terms of control of schizophrenia symptoms over a 3-month period and was more effective than placebo in preventing relapse of schizophrenia.	Added to the Formulary as second choice drug. FC January 2012
07.11.05 *SMC Report No. 208/05*	palonosetron 250micrograms solution for injection (Aloxi®) *Cambridge Laboratories* *Prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.*	Accepted for use: Palonosetron (Aloxi®) is accepted for use within NHS Scotland for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. It is as effective as other 5HT3 antagonists in preventing emesis when given as a single intravenous injection following highly emetogenic chemotherapy (HEC) in the acute phase and moderately emetogenic chemotherapy (MEC) in the acute and delayed phases post-chemotherapy.	Added to the Additional List, for Specialist Use only. FC July 2008
11.02.13 *SMC Report No. 838/13* PRODUCT UPDATE (abbreviated submission)	palonosetron 500microgram soft capsules (Aloxi®) *Sinclair IS Pharma* *Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.*	Accepted for use: palonosetron soft capsules (Aloxi®) is accepted for use within NHS Scotland for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults. At recommended licensed doses the soft capsule formulation has been shown to be clinically non-inferior to the intravenous formulation and is cost neutral. SMC has previously accepted palonosetron intravenous injection for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.	**Included** on the Additional List for the indication in question. FC January 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.06.08 *SMC Report No. 486/08* NON SUBMISSION Superseded by MTA 242 January 2012	panitumumab 20mg/ml concentrate for solution for infusion (Vectibix) *Amgen Ltd* *Treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS (Kirsten rat sarcoma 2 viral oncogene homologue) after failure of fluoropyrimidine -, oxaliplatin -, and irinotecan - containing chemotherapy regimens.*	NOT RECOMMENDED: panitumumab (Vectibix) is not recommended as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS (Kirsten rat sarcoma 2 viral oncogene homologue) after failure of fluoropyrimidine -, oxaliplatin -, and irinotecan - containing chemotherapy regimens. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. MTA 242 Panitumumab monotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.	NOT RECOMMENDED
13.02.12 *SMC Report No. 769/12* NON SUBMISSION	panitumumab (Vectibix®) 20 mg/ml concentrate for solution for infusion *Amgen Ltd* *Treatment of patients with wild-type KRAS metastatic colorectal cancer (mCRC) in first-line in combination with FOLFOX; in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan).*	NOT RECOMMENDED: panitumumab (Vectibix®) is not recommended for use within NHS Scotland for the treatment of patients with wild-type KRAS metastatic colorectal cancer (mCRC) in first-line in combination with FOLFOX; in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.05.05 *SMC Report No. 172/05* PRODUCT UPDATE (abbreviated submission)	paracetamol 500mg/50ml intravenous infusion (Perfalgan®) *Bristol Myers Squibb* *For use in children weighing less than 33kg but more than 10kg for the short-term treatment of moderate pain following surgery, and short-term treatment of fever, when administration by the intravenous route is clinically justified.*	Accepted for use: paracetamol 500mg/50ml intravenous infusion (Perfalgan®) is accepted for use in children weighing less than 33kg but more than 10kg for the short-term treatment of moderate pain following surgery, and short-term treatment of fever, when administration by the intravenous route is clinically justified. This updates SMC advice No. 137/04 which covered other patient groups.	Already in the Formulary.
13.12.04 *SMC Report No. 137/04*	paracetamol infusion (Perfalgan®) *Bristol-Myers Squibb* *Moderate pain following surgery and fever.*	Accepted for use: paracetamol 1g/100mL infusion (Perfalgan®) is accepted for use within NHS Scotland for the short-term treatment of moderate pain following surgery and fever, when administration by intravenous route is clinically justified.	Added to the Formulary, for Specialist Use only. FC February 2005
12.03.07 *SMC Report No. 356/07*	parathyroid hormone 100micrograms powder for injection (Preotact®) *Nycomed Ltd* *For women with severe osteoporosis and at least two prior vertebral fractures or equivalent high risk.*	Restricted use: parathyroid hormone (Preotact®) is accepted for restricted use within NHSScotland for women with severe osteoporosis and at least two prior vertebral fractures or equivalent high risk. It is restricted to initiation by specialists experienced in the treatment of osteoporosis following assessment of fracture risk including measurement of bone mineral density. Parathyroid hormone reduced risks of vertebral fracture compared to placebo. A significant reduction in the incidence of vertebral but not hip fractures has been demonstrated. It has comparable cost effectiveness to an alternative anabolic agent.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2009

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10.01.03 *SMC Report No. 27/02*	parecoxib (Dynastat®) *Pharmacia* *Post-operative pain*	NOT RECOMMENDED: parecoxib is not recommended for use within NHS Scotland. There is no evidence that the parenteral COX-2 selective non-steroidal anti-inflammatory drug (NSAID), parecoxib, is associated with a reduction in clinically significant post-operative haemorrhagic or gastro-intestinal complications compared with the non-selective NSAIDs. Parecoxib is substantially more expensive than non selective NSAIDs and should therefore not replace these drugs. The license holder has indicated their decision to resubmit in light of additional information.	NOT RECOMMENDED
07.07.08 *SMC Report No. 288/06* RESUBMISSION	paricalcitol 5micrograms/mL and 10micrograms/2mL solution for injection (Zemplar®) *Abbott Laboratories* *Prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing haemodialysis.*	NOT RECOMMENDED: paricalcitol (Zemplar®) is not recommended for use within NHS Scotland for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing haemodialysis. The benefits and adverse effects of paricalcitol are similar to another vitamin D analogue with which it has been compared. The economic case has not been demonstrated.	NOT RECOMMENDED.
07.07.08 *SMC Report No. 478/08*	paricalcitol, capsules 1,2 and 4 micrograms (Zemplar®) *Abbott Laboratories* *The prevention and treatment of secondary hyperparathyroidism (SHPT) associated with chronic renal insufficiency (chronic kidney disease [CKD] Stages 3 and 4) patients and chronic renal failure (CKD Stage 5) patients on haemodialysis or peritoneal dialysis.*	NOT RECOMMENDED: paricalcitol capsules 1, 2 and 4 micrograms (Zemplar®) are not recommended for use within NHS Scotland for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal insufficiency (chronic kidney disease [CKD] Stages 3 and 4) patients and chronic renal failure (CKD Stage 5) patients on haemodialysis or peritoneal dialysis. The benefits and adverse effects of paricalcitol capsules compared to other vitamin D analogues have not directly been assessed. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
08.10.12 *SMC Report No. 815/12* NON SUBMISSION	pasireotide (Signifor®) 0.3mg, 0.6 mg and 0.9 mg solution for injection *Novartis Pharmaceuticals Limited* *Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.*	NOT RECOMMENDED: pasireotide (Signifor®) is not recommended for use within NHS Scotland for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.03.11 *SMC Report No. 676/11*	pazopanib 200mg, 400mg film-coated tablets (Votrient®) *GlaxoSmithKline UK* *First-line treatment of advanced renal cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease.*	Restricted use: pazopanib (Votrient®) is accepted for restricted use within NHS Scotland. Indication under review: First-line treatment of advanced renal cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease. SMC restriction: use is restricted to the first-line treatment of advanced RCC. Pazopanib was superior to placebo for the primary endpoint, progression free survival, in the whole population and the treatment naïve and cytokine pre-treated sub-groups. An indirect comparison demonstrated that pazopanib had similar efficacy to the main comparator. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pazopanib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	Added to the Additional List, for Specialist Use only. FC September 2011

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10.12.12 *SMC Report No. 820/12*	pazopanib 200mg, 400mg film-coated tablets (Votrient®) *GlaxoSmithKline UK* *For the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy.*	NOT RECOMMENDED: pazopanib (Votrient®) is not recommended for use within NHS Scotland for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. Efficacy and safety has only been established in certain STS histological tumour subtypes. In a pivotal study, pazopanib significantly improved progression-free survival compared with placebo in adult patients with selective subtypes of advanced STS. However there was no significant improvement in overall survival. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC, and in addition the submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
07.08.06 *SMC Report No. 290/06*	pegaptanib 0.3mg, solution for intravitreal injection (Macugen®) *Pfizer Ltd* *Treatment of neovascular (wet) age-related macular degeneration (AMD).*	Restricted use: pegaptanib for intravitreal injection (Macugen®) is accepted for restricted use within NHS Scotland for the treatment of neovascular (wet) age-related macular degeneration (AMD). It has been shown to reduce the rate of loss of visual acuity in patients with subfoveal neovascular AMD. Pegaptanib should be restricted to patients with visual acuity between 6/12 to 6/60 (inclusive) and should be stopped if visual acuity falls below 6/60 during treatment or where severe visual loss is experienced. The cost effectiveness of pegaptanib in patients who are also receiving photodynamic therapy has, however, not been demonstrated.	Added to the Additional List, for Specialist Use only. FC October 2006
13.10.03 *SMC Report No. 67/03*	pegfilgrastim (Neulasta®) *Amgen Ltd* *Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).*	Restricted use: This sustained release formulation of filgrastim can be used for reducing the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy within the context of current practice guidelines. Pegfilgrastim is a pegylated form of colony stimulating factor (CSF), with a sustained duration of action allowing administration once per chemotherapy cycle. It has benefits of convenience for patients and staff.	Added to the Additional List, for Specialist Use only. FC September 2004
12.06.06 *SMC Report No. 158/05* RESUBMISSION	pegvisomant 10mg, 15mg, 20mg powder and solvent for injection (Somavert®) *Pfizer Ltd* *Acromegaly.*	NOT RECOMMENDED: pegvisomant (Somavert®) is not recommended for use within NHS Scotland for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise insulin-like growth factor 1 (IGF-1) concentrations or was not tolerated. Pegvisomant reduces IGF-1 levels significantly and improves some of the clinical manifestations of acromegaly. It is acknowledged that this is an orphan drug but the economic case has not been demonstrated.	NOT RECOMMENDED
06.09.02 *SMC Report No. 10/02*	pegylated interferon alfa-2a (Pegasys®) *Roche* *Hepatitis C.*	Restricted use: pegylated interferon alfa-2a is an appropriate treatment for the treatment of adult patients which chronic hepatitis C under the overall supervision of specialists experienced in the management of this disorder. This treatment involves a weekly injection from a pre-filled syringe that reduces inconvenience to patients whilst increasing the response rate over interferon alfa-2a alone or in combination with ribavirin.	Approved for use - added to the Additional List. FC March 2003

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11.07.05 *SMC Report No. 186/05*	pegylated interferon alfa 2a, 180micrograms for subcutaneous injection (Pegasys®) *Roche* *Treatment of HBeAg-positive or HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased ALT and histologically verified liver inflammation and/or fibrosis*.	Accepted for use: pegylated interferon alfa 2a (Pegasys®) is accepted for use within NHS Scotland for the treatment of HBeAg-positive or HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased ALT and histologically verified liver inflammation and/or fibrosis. Compared with conventional interferon alfa 2a, it offers comparable efficacy and the convenience of once-weekly rather than three-times weekly subcutaneous administration. It has been shown to be cost effective when compared to a number of comparator medicines in a range of patient groups.	Added to the Additional List, for Specialist Use only. FC July 2007
10.08.09 *SMC Report No. 561/09*	peginterferon alfa-2a, 135 microgram/mL and 180 microgram/mL pre-filled injections of solution for subcutaneous injection (Pegasys®) *Roche Products Limited* *Treatment of chronic hepatitis C in adult patients who have failed previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination therapy with ribavirin.*	Accepted for use: peginterferon alfa-2a (Pegasys®) is accepted for use within NHS Scotland in combination with ribavirin for the treatment of chronic hepatitis C in adult patients who have failed previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin. Non-responders to previous hepatitis C treatment, predominantly with virus genotype 1, achieved sustained viral responses of 8% and 15% following 48 weeks and 72 weeks of combination treatment respectively. The manufacturer did not provide comparative clinical or cost-effectiveness data versus peginterferon alfa-2b.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2011
10.06.13 *SMC Report No. 871/13* PRODUCT UPDATE (abbreviated submission)	pegylated interferon alpha-2a, 135 and 180microgram/mL pre-filled syringe, 135 and 180microgram/mL pre-filled pen (Pegasys®) *Roche Products Limited* *In combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA).*	Restricted use: pegylated interferon alpha-2a (Pegasys®) is accepted for restricted use within NHS Scotland in combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA). When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case-by-case basis. SMC restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology. Results from phase lll studies in paediatric patients suggest that efficacy and safety in this patient group is broadly similar to that in adults, with the exception of the reported effects on growth in children. The Scottish Medicines Consortium has previously accepted this product for restricted use in adults. Pegylated interferon alpha-2a is listed in the British National Formulary for Children 2012-2013 for the treatment of chronic hepatitis C.	Not preferred' in Lothian, as suitable alternatives exist. ViraferonPeg® is the preferred pegylated interferon in children in NHS Lothian FC August 2013
10.05.02 *SMC Report No. 02/02*	pegylated interferon alfa-2b (ViraferonPeg®) *Schering-Plough* *Hepatitis C.*	Restricted use: pegylated interferon alfa-2b (ViraferonPeg®) is an appropriate treatment for the management of adult patients with chronic hepatitis C under the overall supervision of specialists experienced in the management of this disorder. This treatment involves a once weekly injection that reduces inconvenience to patients whilst increasing the response rate to both pegylated interferon alfa-2b alone or in combination with ribavirin.	'Not preferred' as Pegasys® preferred. FC March 2003

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11.08.08 *SMC Report No. 488/08*	pegylated interferon α 2b (ViraferonPeg®), 50, 80, 100, 120 or 150 micrograms powder for solution for injection in pre-filled pen, in combination with ribavirin (Rebetol®), 200mg capsules *Schering-Plough UK and Ireland* *The combination of peginterferon α 2b and ribavirin is indicated in adult patients with chronic hepatitis C who have failed previous treatment with interferon alfa (pegylated or nonpegylated) and ribavirin combination therapy or interferon alfa (pegylated or nonpegylated) monotherapy.*	Accepted for use: pegylated interferon α 2b (ViraferonPeg®) in combination with ribavirin (Rebetol®) is accepted within NHS Scotland for the treatment of adult patients with chronic hepatitis C who have failed previous treatment with interferon alfa (pegylated or non-pegylated) and ribavirin combination therapy or interferon alfa (pegylated or non-pegylated) monotherapy. A sustained virologic response rate of 23% was achieved in a single arm study where relapsed or non-responding patients were treated with peginterferon α 2b and ribavirin. Re-treatment was more cost-effective with patients who had previously responded but relapsed compared to patients who did not respond to initial therapy.	'Not preferred' in Lothian, as suitable alternatives exist. Pegasys® is preferred pegylated interferon for adult patients. FC August 2009
03.07.12 *SMC Report No. 794/12* PRODUCT UPDATE (abbreviated submission)	pegylated interferon alfa-2b 50, 80, 100, 120 or 150 micrograms powder for solution for injection in pre-filled pen (ViraferonPeg®) *MSD Ltd* *In a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA.*	Accepted for use: pegylated interferon alfa-2b (ViraferonPeg®) is accepted for use within NHS Scotland in a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA. This treatment involves a once weekly injection that reduces inconvenience to patients whilst increasing the response rate to pegylated interferon alfa-2b in combination with ribavirin.	**Included** on the Additional List, Specialist Use only, for the indication in question FC August 2013
09.01.04 *SMC Report No. 84/03*	pegylated liposomal doxorubicin (Caelyx®) *Schering-Plough Ltd* *Metastatic breast cancer.*	NOT RECOMMENDED: This pegylated liposomal formulation of doxorubicin hydrochloride is now licensed as monotherapy for the treatment of metastatic breast cancer where there is an increased cardiac risk. An inconclusive study has suggested that it was not inferior to conventional doxorubicin in terms of progression-free survival. It was less cardiotoxic than conventional doxorubicin, but was associated with other troublesome adverse events, particularly palmar-plantar erythrodysesthesia. The product is significantly more expensive than the standard preparation and its cost effectiveness in managing metastatic breast cancer has not been addressed by the company in their submission.	NOT RECOMMENDED
13.07.09 *SMC Report No. 503/08* RESUBMISSION	pegylated liposomal doxorubicin, 2mg/ml concentrate for solution for infusion (Caelyx®) *Schering Plough* *The combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.*	NOT RECOMMENDED: pegylated liposomal doxorubicin (Caelyx®) is not recommended for use within NHS Scotland in combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant. Results from an interim analysis showed that pegylated liposomal doxorubicin plus bortezomib significantly increased the time to disease progression compared to bortezomib monotherapy. At the time of the interim analysis only 31% of patients in the combination arm had reached the primary endpoint. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED

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08.05.06 *SMC Report No. 268/06* NON SUBMISSION	pemetrexed (Alimta®) *Eli Lilly and Company Limited* *Non-small cell lung cancer after prior chemotherapy.*	NOT RECOMMENDED: pemetrexed (Alimta®) is not recommended for use within NHS Scotland as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.09.08 *SMC Report No. 342/07* 2ND RESUBMISSION	pemetrexed, 500mg vial of powder for solution for intravenous infusion (Alimta®) *Eli Lilly and Company Limited* *Monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy.*	Restricted use: pemetrexed (Alimta®) is accepted for restricted use within NHS Scotland for monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. It is restricted to use in patients with good performance status who would otherwise be eligible for treatment with docetaxel. In a retrospective unplanned sub-group analysis of a study comparing pemetrexed with another agent used in the second line treatment of NSCLC, treatment with pemetrexed resulted in an additional median survival of 1.3 months in patients with a non-squamous histology.	Added to the Additional List, for Specialist Use only. FC July 2009
08.02.10 *SMC Report No. 531/09* 2ND RESUBMISSION	pemetrexed, 100mg, 500mg powder for concentrate for solution for infusion (Alimta®) *Eli Lilly and Company Limited* *Pemetrexed in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology.*	Restricted use: pemetrexed (Alimta®) is accepted for restricted use within NHS Scotland in combination with cisplatin for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. It is restricted to patients in whom histology has been confirmed as adenocarcinoma or large cell carcinoma. In a planned subgroup analysis of a study comparing pemetrexed plus cisplatin with another platinum-based combination regimen, treatment with pemetrexed plus cisplatin resulted in an improvement in median survival in patients with a non-squamous (adenocarcinoma plus large cell carcinoma) histology.	Add to the Additional List, for Specialist Use only as first-line treatment FC July 2010
05.08.05 *SMC Report No. 192/05*	pemetrexed 500mg infusion (Alimta®) *Eli Lilly* *Combination chemotherapy for chemotherapy-naïve patients with stage III/IV unresectable malignant pleural mesothelioma.*	Restricted use: pemetrexed (Alimta®) in combination with cisplatin is accepted for restricted use within NHS Scotland for the treatment of chemotherapy-naïve patients with stage III/IV unresectable malignant pleural mesothelioma. Pemetrexed in combination with cisplatin prolonged survival compared with cisplatin alone in patients with unresectable malignant pleural mesothelioma. Pemetrexed is the first licensed agent for the treatment of malignant pleural mesothelioma. Pemetrexed is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy. SMC has not yet received a submission for this indication and therefore cannot currently recommend its use.	Added to the Additional List, for Specialist Use only. FC August 2005

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11.10.10 *SMC Report No. 642/10*	pemetrexed, 100mg, 500mg powder for concentrate for solution for infusion (Alimta®) *Eli Lilly* *Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First-line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel.*	NOT RECOMMENDED: pemetrexed (Alimta®) is not recommended for use within NHS Scotland. Indication under review: monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First-line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel. In a sub-group analysis of patients with non-squamous NSCLC, progression free survival and overall survival (secondary endpoint) were significantly longer for pemetrexed plus best supportive care (BSC) compared to placebo plus BSC. However, the manufacturer did not present a sufficiently robust economic case and their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
13.02.12 *SMC Report No. 770/12* NON SUBMISSION	pemetrexed (Alimta®) 100 mg / 500mg powder for concentrate for solution for infusion *Eli Lilly and Company Limited* *Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.*	NOT RECOMMENDED: pemetrexed (Alimta®) is not recommended for use within NHS Scotland as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. SMC has previously issued not recommended advice for pemetrexed monotherapy for the maintenance treatment of non-small cell lung cancer in patients who have had first line treatment with cisplatin plus gemcitabine, paclitaxel or docetaxel. The marketing authorisation for pemetrexed has recently been extended to allow its use as maintenance therapy in patients who have had first-line treatment with cisplatin plus pemetrexed. The holder of the marketing authorisation has not made a submission to SMC regarding the use of this product in this setting. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.12.12 *SMC Report No. 819/12* Patient Access Scheme	perampanel, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film-coated tablets (Fycompa®) *Eisai Ltd* *Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.*	Restricted use: perampanel (Fycompa®) is accepted for restricted use within NHS Scotland as adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. SMC restriction: use as a second-line adjunctive treatment in patients with refractory partial onset epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. In three placebo-controlled studies in patients with uncontrolled partial-onset seizures, perampanel was superior to placebo in terms of the proportion of patients experiencing a ≥50% reduction in partial seizure frequency per 28 days. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of perampanel. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	**Included** on the Additional List, specialist initiation, for the indication in question. FC April 2013
08.09.03 *SMC Report No. 64/03*	perindopril + indapamide (Coversyl Plus®) *Servier* *Hypertension.*	Accepted for use: perindopril, indapamide (Coversyl Plus®) produces a modest reduction in blood pressure in patients with essential hypertension uncontrolled by perindopril alone. A daily dose of one tablet is almost cost-neutral compared with individual drug preparations.	To remain 'Not preferred' in Lothian for the treatment of hypertension. FC November 2005

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09.06.08 *SMC Report No. 473/08* PRODUCT UPDATE *(abbreviated submission)*	perindopril arginine 2.5mg, 5mg, 10mg tablets (Coversyl Arginine®) *Servier Laboratories Ltd* *Treatment of essential hypertension.*	Accepted for use: perindopril arginine (Coversyl Arginine®) 2.5mg, 5mg, 10mg tablets are accepted for use in NHS Scotland for the treatment of essential hypertension. The 2.5mg and 5mg tablets are also accepted for treatment of symptomatic heart failure. This advice relates to patients for whom perindopril is an appropriate choice of therapy. These preparations are also licensed for the reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation, however this indication has not been reviewed by SMC. The arginine salt replaces a tert-butylamine salt previously available and the 2.5mg, 5mg and 10mg arginine tablets are equivalent to the 2mg, 4mg and 8mg tert-butylamine tablets in terms of the content of perindopril base. Caution is therefore required when prescribing perindopril as the two salts are not dose equivalent. Generic preparations of the tert-butylamine salt are available at a lower cost than the proprietary preparations of perindopril.	'Not preferred' as suitable alternatives exist. FC June 2008.
09.06.08 *SMC Report No. 474/08* PRODUCT UPDATE *(abbreviated submission)*	perindopril arginine 5mg and indapamide 1.25mg tablets (Coversyl Arginine Plus®) *Servier Laboratories Ltd* *Treatment of essential hypertension in patients whose blood pressure is not adequately controlled on perindopril alone and for whom this combination is an appropriate choice of therapy.*	Accepted for use: perindopril arginine 5mg and indapamide 1.25mg tablet (Coversyl Arginine Plus®) is accepted for use in NHS Scotland for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on perindopril alone and for whom this combination is an appropriate choice of therapy. The 5mg perindopril arginine in this formulation is equivalent in terms of the content of perindopril base to the 4mg perindopril tert-butylamine contained in the formulation previously available. After review of a full submission, SMC issued advice on 8th September 2003 that the previously available formulation of perindopril, indapamide (Coversyl Plus®) was recommended for general use within NHS Scotland. It produces a modest reduction in blood pressure in patients with essential hypertension uncontrolled by perindopril alone.	'Not preferred' as suitable alternatives exist. FC June 2008.
07.10.13 *SMC Report No. 897/13*	pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) *Roche Products Limited* *For use in combination with trastuzumab and docetaxel in adult patients with human epidermal growth factor-2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.*	NOT RECOMMENDED: pertuzumab (Perjeta®) is not recommended for use within NHS Scotland for use in combination with trastuzumab and docetaxel in adult patients with human epidermal growth factor-2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. Addition of pertuzumab to current first-line treatment (trastuzumab plus docetaxel) significantly increased progression-free and overall survival for women with HER2-positive metastatic breast cancer. The submitting company did not present a sufficiently robust economic analysis and in addition its justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
09.08.04 *SMC Report No. 35/03* FOLLOWING INDEPENDENT REVIEW PANEL ASSESSMENT	pimecrolimus 1% cream (Elidel®) *Novartis* *Treatment of signs and symptoms of mild-to-moderate atopic dermatitis.*	SMC - not recommended for use. NICE - recommends for use (NICE technology appraisal guidance 82. Tacrolimus and pimecrolimus for atopic eczema. August 2004. www.nice.org.uk/page.aspx?o=TA82) NHS QIS www.nhshealthquality.org/nhsqis advises that NICE technology appraisal 82 recommendations are as valid for Scotland as for England and Wales.	Added to the Additional List, for Specialist Use only. FC January 2005

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.09.05 *SMC Report No. 115/04* RESUBMISSION	pioglitazone 15mg, 30mg, 45mg tablets (Actos®) *Takeda* *Monotherapy for type 2 diabetes mellitus patients for whom metformin is inappropriate.*	Restricted use: pioglitazone (Actos®) is accepted for restricted use within NHS Scotland as monotherapy for type 2 diabetes mellitus patients in whom consideration is otherwise being given to commencing insulin therapy. It is not recommended as monotherapy for any other group of patients. It is one of two peroxisome proliferator-activated receptor-γ agonists marketed in the UK for this indication. Its use should be restricted to patients who have already experienced severe hypoglycaemia or patients in whom metformin and sulphonylureas are contra-indicated or not tolerated.	Added to the Formulary as monotherapy for type 2 diabetes mellitus patients in whom consideration is otherwise being given to commencing insulin therapy. Its use should be restricted to patients who have already experienced severe hypoglycaemia or patients in whom metformin and sulphonylureas are contra-indicated or not tolerated. FC November 2005
11.09.06 *SMC Report No. 252/06* PRODUCT UPDATE (abbreviated submission)	pioglitazone 15mg / metformin 850mg hydrochloride (Competact®) *Takeda UK Ltd* *Treatment of type 2 diabetes mellitus in overweight patients unable to achieve sufficient glycaemic control at their maximally tolerated doses of oral metformin alone.*	Restricted use: pioglitazone 15mg/metformin 850mg hydrochloride (Competact®) is accepted for restricted use in NHSScotland for the treatment of type 2 diabetes mellitus. It should be used for overweight patients who are unable to achieve sufficient glycaemic control at their maximally tolerated doses of oral metformin alone. It is restricted to patients who cannot be treated with a sulphonylurea in combination with metformin. This combination product costs the same as equivalent doses of the individual constituent preparations and offers a more convenient, though less flexible, dosing regimen.	Added to the Additional List. Restricted to use in patients who cannot be treated with a sulphonylurea in combination with metformin in line with SMC recommendations. Combination products should only be considered for use when patients are established on individual drugs and there are concerns about compliance with treatment. FC January 2007
12.03.07 *SMC Report No. 354/07*	pioglitazone 15mg, 30mg and 45mg tablets (Actos® triple therapy) *Takeda UK Ltd* *As triple therapy in combination with metformin and a sulphonylurea, for the treatment of patients (particularly overweight patients) with insufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin.*	Restricted use: pioglitazone (Actos®), as triple therapy in combination with metformin and a sulphonylurea, is accepted for restricted use within NHS Scotland for the treatment of patients (particularly overweight patients) with insufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin. It should be initiated and monitored only by physicians experienced in the treatment of diabetes mellitus who will be able to identify and manage patients who might benefit.	Already included in the Formulary. FC April 2008
10.09.07 *SMC Report No. 399/07*	pioglitazone, 15mg, 30mg and 45mg tablets (Actos®) *Takeda UK Ltd* *Pioglitazone is indicated for combination with insulin in type 2 diabetes mellitus patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance.*	Accepted for use; pioglitazone (Actos®) is accepted for use within NHS Scotland in combination with insulin in type 2 diabetes mellitus patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance. It improved glycaemic control when added to insulin in the relevant patient population.	Already included in the formulary FC October 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.08.13 *SMC Report No: 835/13* RESUBMISSION Patient Access Scheme	pirfenidone 267mg capsule (Esbriet®) *InterMune* *For use in patient with a predicted forced vital capacity (FVC) less than or equal to 80%.*	Restricted use: pirfenidone (Esbriet®) is accepted for restricted use within NHS Scotland in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). SMC restriction: For use in patient with a predicted forced vital capacity (FVC) less than or equal to 80%. Pirfenidone reduced the decline in lung function parameters associated with IPF compared to placebo in a pooled analysis of two similarly designed phase lll studies. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pirfenidone. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC December 2013
18.01.10 *SMC Report No. 594/09*	plerixafor, 20mg/ml solution for injection (Mozobil®) *Genzyme Therapeutics Ltd.* *In combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly.*	Accepted for use: plerixafor (Mozobil®) is accepted for use within NHSScotland in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly. Significantly more patients treated with plerixafor than with placebo achieved their target collection of CD 34+ cells required for autologous stem cell transplantation with subsequent sustained engraftment.	Added to the Additional List, for Specialist Use only. FC August 2010
07.07.14 *SMC Report No. 972/14*	pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) *Celgene Ltd* *In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.*	NOT RECOMMENDED: pomalidomide (Imnovid®) is not recommended for use within NHS Scotland in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Pomalidomide plus dexamethasone significantly increased progression-free survival compared with high-dose dexamethasone in patients with refractory or relapsed and refractory multiple myeloma. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
12.06.06 *SMC Report No. 256/06*	posaconazole 40mg/ml oral suspension (Noxafil®) *Schering Plough* *Treatment of adults with specific invasive fungal infections refractory to or intolerant of specified antifungal agents.*	Accepted for use: posaconazole (Noxafil®) is accepted for use for use within NHS Scotland for the treatment of adults with specific invasive fungal infections refractory to or intolerant of specified antifungal agents. The evidence to support the licensed use of posaconazole is limited to one open-label, non-comparative study mainly in patients refractory to treatment with amphotericin.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
11.06.07 *SMC Report No. 379/07*	posaconazole 40mg/ml oral suspension (Noxafil®) *Schering Plough* *Prophylaxis of invasive fungal infections in immunocompromised patients.*	Restricted use: posaconazole (Noxafil®) is accepted for restricted use within NHS Scotland for prophylaxis of invasive fungal infections in immunocompromised patients. It is restricted to patients in whom there is a specific risk of *Aspergillus* infection or where fluconazole or itraconazole are not tolerated.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC October 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.05.06 *SMC Report No. 247/06*	pramipexole salt 0.125mg, 0.250mg, 1.0mg tablets (Mirapexin®) *Boehringer-Ingelheim* *Symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS).*	Accepted for use: pramipexole (Mirapexin®) is accepted for use within NHS Scotland for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS). It should only be used in patients with a baseline score of 15 points or more on the International Restless Legs Scale (IRLS). In three double blind placebo-controlled studies pramipexole was associated with a 4 to 9-point improvement on the patient-administered 40-point IRL scale in comparison with placebo based on the core clinical features of the syndrome.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC October 2007
07.12.09 *SMC Report No: 580/09* PRODUCT UPDATE (abbreviated submission)	pramipexole dihydrochloride monohydrate prolonged release tablets 0.375mg, 0.75mg, 1.5mg, 3.0mg, 4.5mg (equivalent to 0.26mg, 0.52mg, 1.05mg, 2.1mg, 3.15mg pramipexole) (Mirapexin®) *Boehringer-Ingelheim* *In patients for whom the use of pramipexole is appropriate, the prolonged-release formulation can provide the same daily dose as existing immediate release formulations, with the benefit of once-daily rather than thrice-daily dosing, at an equivalent cost.*	Accepted for use: pramipexole dihydrochloride monohydrate prolonged release tablets 0.375mg, 0.75mg, 1.5mg, 3.0mg, 4.5mg (equivalent to 0.26mg, 0.52mg, 1.05mg, 2.1mg, 3.15mg pramipexole) (Mirapexin®) are accepted for use in NHS Scotland for: treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations).	New formulation of a product already included in the Formulary. FC December 2009
07.09.09 *SMC Report No. 562/09*	prasugrel 5 and 10mg tablets (Efient®) *Daiichi-Sankyo/Eli Lilly and Company Limited* *Prevention of atherothrombotic events in patients with acute coronary syndrome undergoing primary or delayed percutaneous coronary intervention.*	Restricted use: prasugrel (Efient®) co-administered with aspirin is accepted for restricted use within NHS Scotland for the prevention of atherothrombotic events in patients with acute coronary syndrome undergoing primary or delayed percutaneous coronary intervention. Use is restricted to patients who are eligible to receive the 10mg dose of prasugrel. When compared to an alternative antiplatelet agent, prasugrel demonstrated a significant reduction in the incidence of ischaemic events, mainly non-fatal myocardial infarction, in patients with acute coronary syndrome undergoing percutaneous coronary intervention. Prasugrel was, however, also associated with an increased risk of clinically significant bleeding events. Alternative treatments are available at a lower drug acquisition cost.	Added to the Additional List. FC January 2010
13.02.12 SMC Report No. 771/12 NON SUBMISSION	prednisone (Lodotra®) 1 mg, 2 mg and 5 mg modified-release tablets *Napp Pharmaceuticals* *Treatment of moderate to severe, active rheumatoid arthritis in adults particularly when accompanied by morning stiffness.*	NOT RECOMMENDED: prednisone (Lodotra®) is not recommended for use within NHS Scotland for the treatment of moderate to severe, active rheumatoid arthritis in adults particularly when accompanied by morning stiffness. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.12.06 SMC Report No. 339/06 NON SUBMISSION	pregabalin (Lyrica®) *Pfizer Ltd* *Generalised anxiety disorder in adults.*	NOT RECOMMENDED: pregabalin (Lyrica®) is not recommended for use within NHSScotland for generalised anxiety disorder in adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
07.02.05 *SMC Report No. 145/04*	pregabalin 25mg, 50mg, 75mg, 100mg,150mg, 200mg and 300mg capsules (Lyrica®) *Pfizer* *Epilepsy.*	Restricted use: pregabalin (Lyrica®) is accepted for restricted use within NHS Scotland as adjunctive therapy in adults with partial seizures with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.	Added to the Additional List. FC August 2005
11.05.09 *SMC Report No. 157/05* 2nd RESUBMISSION	pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg and 300mg capsules (Lyrica®) *Pfizer* *Treatment of peripheral neuropathic pain in adults.*	Restricted use: pregabalin (Lyrica®) is accepted for restricted use within NHS Scotland for the treatment of peripheral neuropathic pain in adults. The clinical evidence of efficacy in patients with peripheral neuropathic pain who are refractory to treatment was based on open-label, uncontrolled, non-randomised studies, with small patient numbers and different methodologies. Pregabalin is restricted to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments for peripheral neuropathic pain. Treatment should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximally tolerated therapeutic dose.	Added to the LJF as a prescribing note. FC August 2009
13.08.07 *SMC Report No. 389/07*	pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg capsules (Lyrica®) *Pfizer Limited* *For the treatment of central neuropathic pain in adults.*	NOT RECOMMENDED: pregabalin (Lyrica®) is not recommended for use within NHS Scotland for the treatment of central neuropathic pain in adults. In a randomised controlled trial pregabalin was superior to placebo in terms of the primary efficacy variable, the weekly mean pain score. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by the SMC.	NOT RECOMMENDED
11.06.12 *SMC Report No: 765/12* PRODUCT UPDATE (abbreviated submission)	pregabalin oral solution (Lyrica®) *Pfizer Ltd* *For the treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalization and the treatment of Generalised Anxiety Disorder (GAD) in adults.*	Restricted use: pregabalin oral solution (Lyrica®) is accepted for restricted use in NHS Scotland for the treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalization and the treatment of Generalised Anxiety Disorder (GAD) in adults. SMC restriction: pregabalin oral solution should be prescribed only for patients who find it difficult to or are unable to swallow tablets. The following SMC restrictions to the use of pregabalin apply: • Pregabalin is restricted to use in patients with peripheral neuropathic pain who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments for peripheral neuropathic pain. Treatment should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximally tolerated therapeutic dose. • Pregabalin is restricted to use as adjunctive therapy in adults with partial seizures with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance. Pregabalin is not recommended for use in the treatment of Generalised Anxiety Disorder in adults as the company have not made a submission to SMC for use in this indication. Pregabalin oral solution has been shown to be bioequivalent to pregabalin capsules.	**Included** on the LJF for the indication in question. For patients who find it difficult or are unable to swallow tablets Added to the LJF as a prescribing note. FC May 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
17.01.11 *SMC Report No. 665/10*	prilocaine hydrochloride 2% hyperbaric solution for injection (Prilotekal®) *Goldshield Group* *Spinal anaesthesia.*	Restricted use: prilocaine hydrochloride 2% hyperbaric solution for injection (Priloketal®) is accepted for restricted use within NHS Scotland. Indication under review: spinal anaesthesia SMC restriction: for use in spinal anaesthesia in ambulatory surgery settings such as day surgery units. Prilocaine 2% hyperbaric solution for injection was associated with faster discharge times than a hyperbaric formulation of another local anaesthetic in one small single-centre, double-blind, randomised study. Use of this preparation may allow service improvement through benefits to individual patients or service delivery.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC October 2012
12.02.07 *SMC Report No. 340/07*	propiverine hydrochloride 30mg modified release capsule (Detrunorm® XL) *Amdipharm PLC* *Treatment of urinary incontinence, as well as urgency and frequency in patients who have idiopathic detrusor overactivity (overactive bladder)*	Accepted for use: propiverine hydrochloride 30mg modified release capsule (Detrunorm XL®) is accepted for use in NHS Scotland for the treatment of urinary incontinence, as well as urgency and frequency in patients who have idiopathic detrusor overactivity (overactive bladder). For patients for whom propiverine is appropriate it allows once-daily dosing, compared to twice daily dosing with an existing solid oral dose formulation, at no increased cost.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC June 2008
09.01.04 *SMC Report No. 53/03*	propofol 1% (10mg/mg) emulsion of long and medium chain triglycerides (MCT-LCT) (Propofol Lipuro®) *B.Braun* *Anaesthesia.*	Accepted for use: propofol MCT-LCT emulsion 1% is a new formulation of an existing product. It is as effective as alternative formulations of propofol. Pain on injection is significantly reduced in frequency and intensity compared with alternative formulations, though not totally eliminated. The major advantage of this formulation will be realised when co-administration of lignocaine is unnecessary. This advice is based on the assumption that the product will be available through contract at a price that is competitive with available formulations of propofol.	Added to the LJF for Children - Specialist Use only. FC June 2004 Note: propofol MCT-LCT is not in the Adult Formulary. It is 'Not preferred' in adults as effective alternatives are available. FC January 2004
11.07.11 *SMC Report No. 653/10* RESUBMISSION	prucalopride 1mg and 2mg tablet (Resolor®) *Movetis UK* *For symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.*	NOT RECOMMENDED: prucalopride (Resolor) is not recommended for use within NHS Scotland. Indication under review: for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. Overall the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
10.11.08 *SMC Report No. 433/07* PRODUCT UPDATE (abbreviated Submission)	quetiapine 50mg, 200mg, 300mg and 400mg prolonged-release tablet (Seroquel XL®) *AstraZeneca UK Ltd* *The treatment of schizophrenia and manic episodes associated with bipolar disorder.*	Accepted for use: quetiapine prolonged-release tablet (Seroquel XL®) is accepted for use within NHS Scotland for the treatment of schizophrenia and manic episodes associated with bipolar disorder. It is suitable for patients in whom quetiapine is an appropriate choice of antipsychotic. For equivalent doses it has similar or lower costs compared to immediate-release quetiapine.	Added to the Formulary. FC November 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
12.07.04 *SMC Report No. 104/04*	quetiapine (Seroquel®) *AstraZeneca* *Treatment of manic episodes associated with bipolar disorder as monotherapy or as adjunct therapy to mood stabilisers.*	Accepted for use: quetiapine (Seroquel®) is accepted for use within NHS Scotland for the treatment of manic episodes associated with bipolar disorder as monotherapy or as adjunct therapy to mood stabilisers. Active comparators were included in the monotherapy trials but the studies were not designed to show differences between active comparator and quetiapine. It has not been compared to other atypical antipsychotics in this indication. Economic data suggest that quetiapine (Seroquel®) is at least cost neutral, compared to other licensed approaches using atypical antipsychotics in this indication, either as adjunctive therapy or monotherapy.	Already included in the Formulary. FC June 2008
09.05.11 *SMC Report No. 549/09* RESUBMISSION	quetiapine, 25mg, 100mg, 150mg, 200mg, 300mg tablets (Seroquel), quetiapine, 50mg, 150mg, 200mg, 300mg, 400mg sustained release tablets (Seroquel XL) *AstraZeneca* *Treatment of major depressive episodes in the framework of bipolar disorder.*	NOT RECOMMENDED: quetiapine (Seroquel/Seroquel XL) is not recommended for use within NHS Scotland. Indication under review: Treatment of major depressive episodes in bipolar disorder. In monotherapy studies quetiapine was superior to placebo and compared favourably with two active comparators. Efficacy relative to current practice for the management of depression in the framework of bipolar disorder in NHS Scotland involving combination therapy with a mood stabiliser or an atypical antipsychotic plus an antidepressant was not demonstrated. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC. Quetiapine (Seroquel/Seroquel XL) is also licensed for preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment. The manufacturer's submission related only to use in the treatment of major depressive episodes in bipolar disorder. Therefore, SMC cannot recommend its use for preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.	NOT RECOMMENDED
10.10.11 *SMC Report No. 744/11* NON SUBMISSION	quetiapine (Seroquel XL®) 50 mg, 150 mg, 200 mg, 300mg 400 mg prolonged-release tablets *AstraZeneca* *Add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy.*	NOT RECOMMENDED: quetiapine (Seroquel XL®) is not recommended for use within NHS Scotland. Add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
11.08.08 *SMC Report No. 489/08*	rabbit anti-human thymocyte immunoglobulin, 25mg powder for solution for infusion (Thymoglobuline®) *Genzyme Therapeutics Ltd* *Immunosuppression in solid organ transplantation* *-Prevention of graft rejection in renal transplantation* *-Treatment of steroid-resistant graft rejection in renal transplantation* *-Prevention of graft rejection in heart transplantation*	NOT RECOMMENDED: rabbit anti-human thymocyte immunoglobulin, 25mg powder for solution for infusion (Thymoglobuline®) is not recommended for use within NHS Scotland for prevention of graft rejection in renal transplantation. Compared with an alternative agent for induction of immunosuppression it was associated with a lower rate of acute rejection but this did not translate into improved patient or graft survival within the 12-month study period. The manufacturer has not presented a sufficiently robust economic analysis to gain acceptance by SMC. Rabbit anti-human thymocyte immunoglobulin is also licensed for the treatment of steroid resistant graft rejection in renal transplantation and for the prevention of graft rejection in heart transplantation. The manufacturer's submission related only to the prevention of graft rejection in renal transplantation. SMC cannot recommend the use of rabbit anti-human thymocyte immunoglobulin for these additional indications.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product *Manufacturer* *Indication*	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
13.09.04 *SMC Report No. 118/04*	rabeprazole (Pariet®) *Janssen Cilag* *On-demand symptomatic treatment of moderate to severe gastro-oesophageal reflux disease (GORD) in patients without oesophagitis*	Accepted for use: rabeprazole is accepted for use within NHS Scotland for on-demand symptomatic treatment of moderate to severe gastro-oesophageal reflux disease (GORD) in patients without oesophagitis. It is the second proton-pump inhibitor (PPI) with a specific licence for on-demand therapy. Provided that there is a clearly defined need for maintenance therapy following acute treatment of GORD and that rabeprazole is considered to be the most appropriate PPI, on-demand use of rabeprazole is an effective treatment option in patients without oesophagitis.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
13.02.06 *SMC Report No. 232/06* PRODUCT UPDATE (abbreviated submission)	rabeprazole 10mg and 20mg tablet (Pariet®) *Eisai Ltd* *Treatment of Zollinger-Ellison syndrome*	Accepted for use: rabeprazole 10mg and 20mg tablet (Pariet®) is accepted for use within NHS Scotland for the treatment of Zollinger-Ellison syndrome. Other proton pump inhibitors are available for this indication at a lower cost per treatment period.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
10.12.12 *SMC Report No. 818/12*	racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants®, Hidrasec Children®) *Abbott Healthcare Products Ltd* *Complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition.*	NOT RECOMMENDED: racecadotril (Hidrasec Infants®, Hidrasec Children®) is not recommended for use within NHS Scotland for complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition. Racecadotril was significantly better than placebo in reducing mean stool output at 48 hours in children with acute diarrhoea treated in hospital. There is insufficient evidence that it improves recovery rate. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
10.12.12 *SMC Report No. 832/12* NON SUBMISSION	racecadotril (Hidrasec®) 100mg capsules *Abbott Healthcare Products Ltd* *Symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible.*	NOT RECOMMENDED: racecadotril (Hidrasec®) is not recommended for use within NHS Scotland for symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
12.05.08 *SMC Report No. 461/08*	raltegravir, 400mg film-coated tablet (Isentress®) *Merck, Sharp and Dohme Limited* *Treatment of Human Immunodeficiency Virus (HIV-1) infection in treatment experienced adult patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy*	Restricted use: raltegravir, 400mg film-coated tablet (Isentress®) is accepted for restricted use within NHS Scotland in combination with other antiretroviral medicinal products agents for the treatment of Human Immunodeficiency Virus (HIV-1) infection in treatment experienced adult patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. It is restricted to patients with triple class resistant HIV-1 infection. Addition of raltegravir to optimised background therapy in treatment experienced patients with documented resistance to at least one drug in each of the three HIV antiviral classes, significantly increased the number of patients achieving clinically significant reductions in viral load.	Added to the Additional List, for Specialist Use only. FC July 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.05.10 *SMC Report No: 613/10*	raltegravir, 400mg film-coated tablet (Isentress®) *Merck, Sharp and Dohme Limited* *In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients.*	Restricted use: raltegravir (Isentress®) is accepted for restricted use within NHS Scotland. Licensed indication under review: in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients. SMC restriction: to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions. Raltegravir has been shown to be non-inferior to efavirenz in combination with tenofovir and emtricitabine in treatment naïve patients. In two small open-label studies, raltegravir demonstrated maintenance of viral suppression over 24 weeks when substituted for enfuvirtide in a combination regimen in highly pre-treated patients with a history of triple class failure or intolerance. The health economic case was demonstrated only for a sub-population of patients within the licensed indication. SMC has previously issued advice for raltegravir in the treatment of HIV infection and this extends the advice to cover a wider patient population.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2011
09.09.13 *SMC Report No. 902/13* PRODUCT UPDATE (Abbreviated submission)	raltegravir 25mg, 100mg chewable and 400mg film-coated tablets (Isentress®) *MSD Ltd* *In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years.*	Restricted use: raltegravir (Isentress®) is accepted for restricted use within NHS Scotland in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years. SMC restriction: to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir should to be prescribed under the supervision of specialists in paediatric HIV. The chewable and film-coated tablets are not bioequivalent and therefore are not interchangeable. SMC has previously accepted raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.	**Included** on the Additional List, Specialist Use only for the indication in question. FC August 2013
11.06.07 *SMC Report No. 381/07*	ranibizumab 10mg/ml solution for intravitreal injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* *Treatment of neovascular (wet) age-related macular degeneration (AMD)*	Accepted for use: ranibizumab (Lucentis®) is accepted for use within NHS Scotland for the treatment of neovascular (wet) age-related macular degeneration (AMD). Ranibizumab reduces the rate of visual acuity loss and increases visual acuity. It should be stopped if visual acuity falls persistently below 6/60 during treatment.	Added to the Additional List, for Specialist Use only. FC July 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.12.12 *SMC Report No. 711/11* RESUBMISSION Patient Access Scheme	ranibizumab, 10mg/mL solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* *Treatment of visual impairment due to diabetic macular oedema in adults.*	Restricted use: ranibizumab (Lucentis®) is accepted for restricted use within NHS Scotland for the treatment of visual impairment due to diabetic macular oedema (DMO) in adults. SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline. Ranibizumab significantly improved visual acuity over 12 months compared with standard laser photocoagulation treatment. Open label extension results up to 3 years suggest maintenance of effect. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC January 2013
07.11.11 *SMC Report No. 732/11* Patient Access Scheme	ranibizumab, 10mg/mL solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* *For the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults.*	Restricted use: ranibizumab (Lucentis®) is accepted for restricted use within NHS Scotland for the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. SMC restriction: restricted to use in patients with macular oedema secondary to central retinal vein occlusion (CRVO). Ranibizumab was associated with significant improvements in visual acuity during 6-month sham-controlled treatment in one study in patients with branch retinal vein occlusion and in one study in patients with central retinal vein occlusion. The benefits were considerable in patients with CRVO and there is a lack of alternative treatment options for these patients. The submitting company did not present a sufficiently robust economic analysis for ranibizumab in the treatment of BRVO to gain acceptance by SMC.	Added to the Additional List, for Specialist Use only, for CRVO. FC December 2011 See also entry below
13.05.13 *SMC Report No. 732/11* RESUBMISSION Patient Access Scheme	ranibizumab, 10mg/mL solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* *For the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. This resubmission relates to branch RVO only.*	Accepted for use: ranibizumab (Lucentis®) is accepted for use within NHS Scotland for the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. This resubmission relates to branch RVO only. Ranibizumab was associated with significant improvements in visual acuity during 6-month sham-controlled treatment in a phase III randomised double-blind study in patients with branch retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. SMC has previously accepted ranibizumab for use in macular oedema secondary to central retinal vein occlusion (CRVO). This advice now extends its use to patients with branch retinal vein occlusion (BRVO).	**Included** on the Additional List, Specialist Us only, for the indication in question. FC July 2013 See also entry above

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
11.11.13 *SMC Report No. 907/13* Patient Access Scheme	ranibizumab, 10mg/mL, solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* *Treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults.*	Accepted for use: ranibizumab (Lucentis®) is accepted for use within NHS Scotland as treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults. In patients with choroidal neovascularisation secondary to pathologic myopia, ranibizumab intravitreal injection was associated with a significant improvement in visual acuity of 8.4 Early Treatment Diabetic Retinopathy Study letters at three months compared with photodynamic therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC December 2013
12.11.12 *SMC Report No. 565/09* INDEPENDENT REVIEW PANEL ASSESSMENT	ranolazine, 375mg, 500mg and 750mg prolonged-release tablets (Ranexa®) *A Menarini Pharma UK SRL* *As add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists).*	NOT RECOMMENDED: ranolazine (Ranexa®) is not recommended for use within NHS Scotland. Indication under review: as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists). When added to standard doses of antianginal drugs, ranolazine increased exercise duration at trough drug levels compared with placebo after 12 weeks treatment. Although significant, the effect size was modest, but not uncommon in studies of patients with stable angina pectoris. The submitting company did not present a sufficiently robust clinical and economic case to gain acceptance by the Independent Review Panel (IRP).	NOT RECOMMENDED
11.12.06 *SMC Report No. 243/06* RESUBMISSION	rasagiline 1mg tablet (Azilect®) *Lundbeck Ltd / Teva Pharmaceuticals Ltd* *Treatment of idiopathic Parkinson's disease as monotherapy (without levodopa).*	NOT RECOMMENDED: rasagiline (Azilect®) is not recommended within NHS Scotland for the treatment of idiopathic Parkinson's disease as monotherapy (without levodopa). Rasagiline provides modest symptomatic improvement for patients with early Parkinson's disease. The economic case has not been demonstrated.	NOT RECOMMENDED
11.12.06 *SMC Report No. 255/06* RESUBMISSION	rasagiline 1mg tablet (Azilect®) *Lundbeck Ltd / Teva Pharmaceuticals Ltd* *Treatment of idiopathic Parkinson's disease as adjunct therapy (with levodopa) in patients with end of dose fluctuations.*	NOT RECOMMENDED: rasagiline (Azilect®) is not recommended within NHS Scotland for the treatment of idiopathic Parkinson's disease as adjunct therapy (with levodopa) in patients with end of dose fluctuations. Rasagiline reduces off-time in patients with Parkinson's disease and end of dose fluctuations on levodopa, similar to reductions shown with the less effective of two currently marketed catechol-O-methyl transferase inhibitors. The economic case has not been demonstrated.	NOT RECOMMENDED
07.04.08 *SMC Report No. 472/08* NON SUBMISSION	retapamulin (Altargo®) *GlaxoSmithKline UK* *Short term treatment of the following superficial skin infections:* *impetigo and infected small lacerations, abrasions, or sutured wounds.*	NOT RECOMMENDED: retapamulin (Altargo®) is not recommended for use within NHSScotland for the short term treatment of the following superficial skin infections: impetigo and infected small lacerations, abrasions, or sutured wounds. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.07.11 *SMC Report No. 712/11*	retigabine, 50mg, 100mg, 200mg, 300mg and 400mg film-coated tablets (Trobalt®) *GlaxoSmithKline* *Adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy.*	Restricted use: retigabine (Trobalt®) is accepted for restricted use within NHS Scotland. Indication under review: Adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. SMC restriction: patients with refractory epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. In two placebo-controlled studies in patients with refractory epilepsy retigabine was superior to placebo in terms of the proportion of patients experiencing ≥ 50% reduction in partial seizure frequency per 28 days. An indirect comparison indicates that retigabine has similar efficacy to two other antiepileptic drugs used as adjunctive therapy.	Added to the Additional List. FC January 2012
13.05.13 *SMC Report No. 876/13* NON SUBMISSION	rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®) Film-coated Tablets *Genus Pharmaceuticals* *Initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines.*	NOT RECOMMENDED: rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®) is not recommended for use within NHS Scotland for initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.08.12 *SMC Report No. 808/12* NON SUBMISSION	rifaximin 200 mg film-coated tablets (Xifaxanta®) *Norgine Limited* *Treatment of travellers' diarrhoea that is not associated with any of:* • *Fever* • *Bloody diarrhoea* • *Eight or more unformed stools in the previous 24 h* • *Occult blood or leucocytes in the stool.*	NOT RECOMMENDED: rifaximin 200 mg film coated tablets (Xifaxanta®) is not recommended for use within NHS Scotland for the treatment of travellers' diarrhoea that is not associated with any of: • Fever • Bloody diarrhoea • Eight or more unformed stools in the previous 24 h • Occult blood or leucocytes in the stool. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.09.13 *SMC Report No. 893/13*	rifaximin 550mg film-coated tablets (Targaxan®) *Norgine Pharmaceuticals Ltd* *Reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age.*	Accepted for use: rifaximin (Targaxan®) is accepted for use within NHS Scotland for reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age. In a double-blind randomised controlled study of six months duration, rifaximin was superior to placebo for the primary outcome of time to first overt breakthrough episode of HE.	**Included** on the Additional List, Specialist Initiation, for the indication in question. FC October 2013
13.02.12 *SMC Report No. 758/12*	rilpivirine 25mg film-coated tablet (Edurant®) *Janssen-Cilag* *In combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL.*	Accepted for use: rilpivirine (Edurant®) is accepted for use within NHS Scotland in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL. The non-inferiority of rilpivirine over another non-nucleoside reverse transcriptase inhibitor (when given in combination with two nucleoside reverse transcriptase inhibitors) for virological response was demonstrated in two phase III, comparative, multi-centre studies in antiretroviral treatment-naïve patients.	Added to the Additional List for Specialist Use only. **Included** on the Lothian Joint Formulary for the indication in question. FC April 2012

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.04.14 *SMC Report No. 951/14*	rilpivirine 25mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®) *Gilead Sciences Ltd.* *Treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load ≤100,000 HIV-1 RNA copies/mL.*	Accepted for use: rilpivirine, emtricitabine, tenofovir disoproxil fumarate tablet (Eviplera®) is accepted for use within NHS Scotland for the treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load ≤100,000 HIV-1 RNA copies/mL. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®. Rilpivirine, emtricitabine, tenofovir (Eviplera®) maintained virological suppression in patients switched from other antiretroviral regimens. There is no evidence of efficacy in patients switching from other antiretroviral regimens due to virological failure. SMC issued advice in February 2012 regarding the use of Eviplera® in antiretroviral treatment-naive adult patients. The current advice extends use to antiretroviral treatment-experienced patients.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC May 2014
12.02.07 *SMC Report No. 341/07*	rimonabant 20mg tablet (Acomplia®) *Sanofi-Aventis* *As an adjunct to diet and exercise for the treatment of obese patients (body mass index (BMI) =30kg/m^2), or overweight patients (BMI >27kg/m^2) with an associated risk factor or risk factors such as type 2 diabetes or dyslipidaemia.*	NOT RECOMMENDED: rimonabant (Acomplia®) is not recommended for use within NHS Scotland as an adjunct to diet and exercise for the treatment of obese patients (body mass index (BMI) =30kg/m^2), or overweight patients (BMI >27kg/m^2) with an associated risk factor or risk factors such as type 2 diabetes or dyslipidaemia. Rimonabant was associated with a reduction in mean weight of about 4-5kg over that with placebo. However, this weight was generally regained within one year of stopping treatment. The economic case has not been demonstrated. The licence holder has indicated their decision to resubmit.	NOT RECOMMENDED WITHDRAWN FROM THE MARKET
09.05.03 *SMC Report No. 46/03* PRODUCT UPDATE	risedronate sodium (Actonel®) *Proctor & Gamble, Aventis (Joint marketing)* *Prophylaxis and treatment of osteoporosis in post menopausal women.*	Accepted for use: risedronate sodium (Actonel®) is a once weekly formulation which offers a convenient, cost neutral alternative to once daily medication for the prophylaxis and treatment of osteoporosis in post menopausal women.	Approved for use - added to the Formulary as first choice. FC June 2004
10.12.07 *SMC Report No. 424/07* NON SUBMISSION	risedronate sodium (Actonel®) *Procter & Gamble Pharmaceuticals UK Ltd* *Treatment of osteoporosis in men at high risk of fractures.*	NOT RECOMMENDED: risedronate sodium (Actonel®) is not recommended for use within NHSScotland for the treatment of osteoporosis in men at high risk of fractures. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.08.04 *SMC Report No. 113/04*	risperidone (Risperdal®) *Janssen-Cilag* *Treatment of episodes of mania in bipolar disorder.*	Accepted for use: risperidone (Risperdal®) is accepted for use within NHS Scotland for the treatment of episodes of mania in bipolar disorder. Risperidone has similar efficacy to haloperidol in improving symptom scores, with fewer extrapyramidal side effects. In an economic model based on indirect comparison, monotherapy with risperidone appears to be cost effective. No evidence is submitted on its cost effectiveness profile in co-therapy.	Already included in the formulary. FC June 2008
09.05.03 *SMC Report No. 41/03*	risperidone orodispersible tablets (Risperdal Quicklet®) *Janssen-Cilag Ltd* *Treatment of acute and chronic schizophrenia and other similar psychotic conditions.*	Restricted use: Use of Risperdal Quicklet®, for the treatment of acute and chronic schizophrenia and other similar psychotic conditions, should be reserved for those patients in whom rapid oral absorption is indicated.	Approved for use - added to the Formulary. Reserved for the treatment of acute episodes of schizophrenia in patients who are unco-operative or wary of taking oral medication. Not intended for long-term use. FC May 2003

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
06.12.02 *SMC Report No. 22/02*	risperidone prolonged release injection (Risperdal Consta®) *Janssen-Cilag Ltd* *Schizophrenia.*	Restricted use: Risperdal Consta® may be considered as a treatment option for patients who require an atypical antipsychotic and for whom depot injection is the preferred route of administration. Its use should be under the overall supervision of a consultant psychiatrist.	Approved for use - added to the Additional List. Specialist prescribing only, not primary care. FC March 2003
10.09.07 *SMC Report No. 403/07* PRODUCT UPDATE (Abbreviated submission)	risperidone 3mg, 4mg orodispersible tablets (Risperdal Quicklet®) *Janssen-Cilag Ltd* *Treatment of acute and chronic schizophrenia and similar psychosis and treatment of mania in bipolar disorder.*	Restricted use: risperidone 3mg, 4mg orodispersible tablets (Risperdal Quicklet®) are accepted for restricted use within NHS Scotland for treatment of acute and chronic schizophrenia and similar psychosis and treatment of mania in bipolar disorder. These new strengths of risperidone orodispersible tablets should be used in patients for whom risperidone is an appropriate choice of antipsychotic and an orodispersible tablet is an appropriate formulation.	New formulation of a drug already included in the Formulary. FC October 2007
07.03.03 *SMC Report No. 33/03*	rituximab (MabThera®) *Roche* *Lymphoma.*	Restricted use: rituximab is recommended for use by oncologists or haematologists in Scotland who have expertise in treating lymphoma. It should be administered in a hospital environment where full resuscitation facilities are available.	Added to the Formulary as a Prescribing Note, for Specialist Use only. FC September 2004
13.12.04 *SMC Report No. 135/04*	rituximab (MabThera®) *Roche* *Treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with cyclophosphamide, vincristine and prednisolone (CVP) chemotherapy.*	Accepted for use: rituximab is accepted for use within NHS Scotland for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with cyclophosphamide, vincristine and prednisolone (CVP) chemotherapy. Rituximab is for use only by oncologists or haematologists who have expertise in treating lymphoma. It should be administered in a hospital environment where full resuscitation facilities are available. Limited results show that rituximab plus CVP significantly increased the time to treatment failure compared with CVP alone.	Added to the Formulary as a Prescribing Note, for Specialist Use only. FC March 2005
11.12.06 *SMC Report No. 330/06*	rituximab 10mg/ml concentrate for infusion (MabThera®) *Roche* *Maintenance therapy for patients with relapsed/refractory follicular lymphoma responding to induction therapy with chemotherapy with or without rituximab.*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland as maintenance therapy for patients with relapsed/refractory follicular lymphoma responding to induction therapy with chemotherapy with or without rituximab. In a phase lll, randomised, open-label study, rituximab maintenance treatment significantly increased the median progression-free survival from 15 months in the observation arm to 52 months in the rituximab arm with an increase in overall survival at three years. This prolonged survival requires to be confirmed in longer term follow up. Rituximab is restricted for use only by oncologists or haematologists who have expertise in treating lymphoma.	Added to the Additional List, for Specialist Use only. FC May 2007
13.11.06 *SMC Report No. 323/06*	rituximab 100mg/10mL, 500mg/50mL solution for intravenous infusion (MabThera®) *Roche* *In combination with methotrexate for treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARDs) including one or more tumour necrosis factor (TNF) inhibitor.*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland in combination with methotrexate for treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARDs) including one or more tumour necrosis factor (TNF) inhibitor. It is restricted to use by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis. Rituximab in combination with methotrexate improves signs and symptoms and quality of life and prevents joint damage compared to methotrexate, in adults with rheumatoid arthritis who have had an inadequate response to methotrexate and an inadequate response or intolerance to at least one TNF-antagonist. Treatment should only be repeated in patients who continue to achieve an American College of Rheumatology (ACR) response of at least 20. Rituximab is cost effective if the average dosing interval for those patients who respond to initial treatment does not fall below six months.	To remain on the Additional List, for Specialist Use only (now a licensed indication). FC January 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
08.09.08 *SMC Report No. 493/08*	rituximab, 100mg and 500mg concentrate for solution for infusion (MabThera®) *Roche* *Treatment of previously untreated patients with stage III to IV follicular lymphoma in combination with chemotherapy.*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland for the treatment of previously untreated patients with stage III to IV follicular lymphoma in combination with chemotherapy. Rituximab added to a number of different chemotherapy regimens produced statistically significant improvements in the primary study endpoints when compared with the chemotherapy regimens alone. Rituximab is restricted to use only by haematologists or oncologists who have expertise in treating lymphoma. It should be administered in a healthcare environment where full resuscitation facilities are available. SMC issued advice in December 2004 regarding the use of rituximab in combination with cyclophosphamide, vincristine and prednisolone (CVP) chemotherapy for the treatment of previously untreated patients with stage III to IV follicular lymphoma. The current advice extends the range of chemotherapy regimens that can be used in combination with rituximab for this indication.	Added to the Additional List, for Specialist Use only. FC March 2011
08.06.09 *SMC Report No. 540/09*	rituximab, 100mg and 500mg concentrate for solution for infusion (MabThera®) *Roche* *First-line treatment of patients with chronic lymphocytic leukaemia (CLL) in combination with chemotherapy.*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland for first-line treatment of patients with chronic lymphocytic leukaemia (CLL) in combination with fludarabine and cyclophosphamide. Rituximab in combination with fludarabine and cyclophosphamide resulted in significantly longer progression free survival than fludarabine and cyclophosphamide alone. The patient population in the pivotal clinical study had an Eastern Cooperative Oncology Group Performance Status of 0 or 1 and was a younger population than that generally seen in practice. Evidence in patients over 70 years of age is limited. Rituximab is restricted to use by specialists in haematology and haemato-oncology.	Added to the Additional List, for Specialist Use only. FC December 2009
18.01.10 *SMC Report No. 591/09*	rituximab, 100mg and 500mg concentrate for solution for infusion (MabThera®) *Roche* *Treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia, in combination with chemotherapy.*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland. Licensed indication under review: for the treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia (CLL) in combination with chemotherapy. Rituximab in combination with fludarabine and cyclophosphamide resulted in significantly longer progression-free survival than fludarabine and cyclophosphamide alone. The patient population in the pivotal clinical study had an Eastern Cooperative Oncology Group Performance Status of 0 or 1 and was a younger population than that generally seen in clinical practice. Evidence in patients over 70 years of age is limited. Restriction: Rituximab is restricted to use by specialists in haematology and haemato-oncology.	Added to the Additional List, Specialist Use only. FC April 2011
07.02.11 *SMC Report No. 675/11*	rituximab, 100mg in 10mL, 500mg in 50mL, concentrate for solution for infusion (MabThera®) *Roche Products Limited* *Rituximab maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland. Indication under review: Rituximab maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. SMC restriction: for maintenance treatment in follicular lymphoma patients who have responded to induction with rituximab plus chemotherapy. Rituximab significantly increased progression free survival following a response to induction therapy in patients with previously untreated follicular lymphoma compared with observation alone. Longer follow up is required to establish benefit in overall survival.	Added to the Additional List, for Specialist Use only. FC March 2011

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.09.13 *SMC Report No. 894/13*	rituximab 100mg, 500mg solution for infusion (MabThera®) *Roche Products Limited* *In combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA).*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland in combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). SMC restriction: to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide. One course of rituximab (an intravenous infusion weekly for four weeks) was non-inferior to three to six months of oral cyclophosphamide for the proportion of patients achieving remission at six months. The study was conducted in patients with severe proteinase 3- or myeloperoxidase-antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis who were treatment-naïve or previously treated.	**Included** on the Additional List, Specialist Use only, for the indication in question. FC October 2013 and FC November 2013
07.07.14 *SMC Report No. 975/14* Patient Access Scheme	rituximab 1400mg solution for subcutaneous injection (Mabthera®) *Roche Products Limited* *For non-Hodgkin's lymphoma (NHL) in adults.*	Restricted use: rituximab subcutaneous injection (Mabthera®) is accepted for restricted use within NHS Scotland for non-Hodgkin's lymphoma (NHL) in adults: - previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy; - maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy; - treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy. SMC restriction: Subcutaneous rituximab is accepted for use in line with previous SMC advice for intravenous rituximab i.e. accepted within licensed indication as above except in the maintenance setting, where use is restricted to patients who have responded to induction therapy with rituximab plus chemotherapy. In two pharmacokinetic-based clinical bridging studies, rituximab subcutaneous injection was shown to be non inferior to rituximab intravenous infusion for trough concentration and area under the concentration time curve. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of rituximab subcutaneous injection. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Formulary classification not yet decided – waiting for information from clinician.
12.01.09 *SMC Report No. 519/08*	rivaroxaban 10mg film-coated tablets (Xarelto®) *Bayer Schering Pharma* *Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.*	Accepted for use: rivaroxaban (Xarelto®) is accepted for use within NHS Scotland for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. In three large phase III studies in patients undergoing either total knee or total hip replacement surgery, rivaroxaban was superior to low molecular weight heparin in reducing the incidence of VTE and all cause mortality with patients while having a similar incidence of major bleeding events.	Added to the Formulary, as first choice for the primary prevention of venous VTE in adult patients undergoing elective total hip or knee replacements. Prescribing to be in Secondary care only. FC December 2008

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13.02.12 *SMC Report No. 755/12*	rivaroxaban 15 and 20mg film-coated tablets (Xarelto®) *Bayer PLC* *For treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.*	Accepted for use: rivaroxaban (Xarelto®) is accepted for use within NHS Scotland for the treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults. Rivaroxaban has been shown to be non-inferior to standard anticoagulant therapy including a low molecular weight heparin in combination with a vitamin K antagonist for the treatment of proximal DVT and prevention of recurrence. Experience with rivaroxaban in this indication for more than 12 months is limited therefore the cost-effectiveness of indefinite treatment has not been demonstrated.	**Included** on the LJF as a first choice drug, for the indication in question. The treatment will be initiated by secondary care in line with the treatment protocol. FC June 2013
13.02.12 *SMC Report No. 756/12*	rivaroxaban 15 and 20mg film-coated tablets (Xarelto®) *Bayer PLC* *For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.*	Restricted use: rivaroxaban (Xarelto®) is accepted for restricted use within NHS Scotland, for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. SMC restriction: Rivaroxaban is accepted for use in patients who have poor INR control despite evidence that they are complying with a coumarin anticoagulant and in patients who are allergic to or unable to tolerate coumarin anticoagulants. Rivaroxaban was non-inferior to standard oral anticoagulation at preventing stroke or systemic embolism in one large, double-blind study in patients with atrial fibrillation and moderate to high risk of stroke. This was not associated with a significantly increased risk of major or non-major clinically relevant bleeding. The submitting company made an economic case for rivaroxaban use in the restricted patient population described above.	**Not included** pending protocol. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2012
11.03.13 *SMC Report No. 852/13*	rivaroxaban 15mg and 20mg film-coated tablets (Xarelto®) *Bayer plc* *Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults.*	Accepted for use: rivaroxaban (Xarelto®) is accepted for use within NHS Scotland for the treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults. Rivaroxaban was non-inferior to a regimen including a low molecular weight heparin and a vitamin K antagonist for the treatment of PE and the prevention of recurrence of DVT or PE. Duration of treatment was 3, 6 or 12 months at the discretion of the treating physician. Experience with rivaroxaban in this indication for more than 12 months is limited therefore the cost-effectiveness of indefinite treatment has not been demonstrated.	**Included** on the LJF as a first choice drug for patients meeting the selection criteria, for Specialist Initiation, for the indication in question. FC May 2014
07.08.06 *SMC Report No. 310/06* NON SUBMISSION	rivastigmine (Exelon®) *Novartis Pharmaceuticals UK Ltd* *Treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease.*	NOT RECOMMENDED: rivastigmine (Exelon®) is not recommended for use within NHSScotland for the treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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12.11.07 *SMC Report No. 414/07* PRODUCT UPDATE (abbreviated submission)	rivastigmine 4.6mg/24h and 9.5mg/24h transdermal patch (Exelon®) *Novartis Pharmaceuticals UK Limited* *Symptomatic treatment of moderately severe Alzheimer's dementia only.*	Restricted use: rivastigmine transdermal patch (Exelon®) is accepted for restricted use within NHS Scotland for symptomatic treatment of moderately severe Alzheimer's dementia only. It should be used in accordance with guidance from NHS Quality Improvement Scotland on the application of the National Institute for Health and Clinical Excellence (NICE) technology appraisal number 111. Within this context it is suitable for patients in whom rivastigmine is an appropriate choice of acetylcholinesterase inhibitor and in whom a transdermal patch is an appropriate choice of formulation.	Added to the LJF as a 'new formulation of a drug already in the formulary'. FC December 2007
11.10.10 *SMC Report No. 635/10*	roflumilast 500 microgram tablets (Daxas®) *Nycomed Ltd* *Maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in 1 second [FEV1] post-bronchodilator <50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.*	NOT RECOMMENDED: roflumilast (Daxas®) is not recommended for use within NHS Scotland. Indication under review: maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in 1 second [FEV1] post-bronchodilator <50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment. Roflumilast has been associated with improved lung function and reduced the rate of moderate and severe COPD exacerbations compared to placebo in studies of patients representing the licensed population. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.10.09 *SMC Report No. 553/09*	romiplostim, 250 microgram vial of powder for solution for subcutaneous injection (Nplate®) *Amgen* *Adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Romiplostim may be considered as second line treatment for adult non-splenectomised patients where surgery is contra-indicated.*	Restricted use: romiplostim (Nplate®) is accepted for restricted use within NHS Scotland for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Romiplostim is also accepted for restricted use as second line treatment for adult non-splenectomised patients where surgery is contra-indicated. Romiplostim is restricted to use in patients with severe symptomatic ITP or patients with a high risk of bleeding. Romiplostim was significantly better than placebo in maintaining platelets at (or above) a minimum target level in previously treated patients with ITP.	'Not preferred' in Lothian as suitable alternatives exist. FC November 2011
10.07.06 *SMC Report No. 165/05* RESUBMISSION	ropinirole tablets (Adartrel®) *GlaxoSmithKline* *New indication: moderate to severe restless legs syndrome*	Restricted use: ropinirole (Adartrel®) is accepted for restricted use within NHS Scotland for the treatment of moderate to severe idiopathic restless legs syndrome (RLS). Its use should be restricted to patients with a baseline score of 24 points or more on the International Restless Legs Scale (IRLS). Compared with placebo, ropinirole was associated with a 4-point improvement on the 40-point IRLS in a pooled analysis restricted to patients with IRLS score of 24 points.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010

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08.09.08 *SMC Report No. 491/08* PRODUCT UPDATE (abbreviated submission)	ropinirole 2 mg, 4 mg or 8 mg prolonged-release tablets (Requip® XL) *GlaxoSmithKline* *Treatment of idiopathic Parkinson's disease in patients already taking ropinirole immediate release tablets and in whom adequate symptomatic control has been established*	Accepted for use: ropinirole 2 mg, 4 mg, 8 mg prolonged-release tablets (Requip® XL) are accepted for use in NHS Scotland for the treatment of idiopathic Parkinson's disease in patients already taking ropinirole immediate release tablets and in whom adequate symptomatic control has been established. Substitution of ropinirole prolonged release tablets for ropinirole immediate release tablets may be used as: Monotherapy, alone (without levodopa) in idiopathic Parkinson's disease, or as: Adjunctive therapy in addition to levodopa to control 'on-off' fluctuations which might permit a reduction in the total daily dose of levodopa. Substitution of prolonged-release ropinirole for ropinirole immediate release tablets should be supervised by appropriate specialists in Parkinson's disease.	Added to the Formulary as a Prescribing Note, for Specialist Use only. FC August 2008
09.08.04 *SMC Report No.91/04* RESUBMISSION	rosiglitazone (Avandia®) *GlaxoSmithKline* *Monotherapy for type 2 diabetes mellitus patients for whom metformin is inappropriate*	Restricted use: rosiglitazone (Avandia®) is accepted for restricted use within NHS Scotland as monotherapy for type 2 diabetes mellitus patients in whom consideration is otherwise being given to commencing insulin therapy. It is not recommended as monotherapy for any other group of patients. It is one of two peroxisome proliferator-activated receptor-γ agonists recently marketed in the UK for this indication. Its use should be confined to patients who have already experienced severe hypoglycaemia or who are intolerant of metformin and sulphonylureas.	Already included in the Formulary FC April 2008 WITHDRAWN FROM THE MARKET October 2010
13.06.05 *SMC Report No. 181/05* PRODUCT UPDATE (abbreviated submission)	rosiglitazone maleate (Avandia Triple Therapy®) *GlaxoSmithKline* *Triple oral therapy in combination with metformin and a sulphonylurea in patients (particularly overweight patients) who are unable to achieve sufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin*	Restricted use: rosiglitazone (Avandia®) is accepted for restricted use in NHS Scotland as triple oral therapy in combination with metformin and a sulphonylurea in patients (particularly overweight patients) who are unable to achieve sufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin. It should be initiated and monitored only by physicians experienced in the treatment of diabetes mellitus who will be able to identify and manage patients who might benefit.	Added to the Formulary as a Prescribing Note. FC April 2006 WITHDRAWN FROM THE MARKET October 2010
13.12.04 *SMC Report No. 140/04* PRODUCT UPDATE (abbreviated submission)	rosiglitazone maleate / metformin hydrochloride (Avandamet®) *GlaxoSmithKline* *Type 2 diabetes mellitus*	Accepted for use: New formulation of existing combination. Rosiglitazone maleate/metformin hydrochloride (Avandamet®) in the undernoted formulations is accepted for use in NHSScotland for the treatment of Type 2 diabetes mellitus in patients for whom a combination of rosiglitazone and metformin is appropriate. The new formulations facilitate dosage adjustment and, at a given dose combination, are not associated with increased cost compared with existing formulations. As previously stated by SMC (February 2004), Avandamet® may be used for overweight patients who are unable to achieve sufficient glycaemic control at their maximally tolerated doses of oral metformin alone, and cannot be treated with a sulphonylurea in combination with metformin. Rosiglitazone maleate 2mg and metformin hydrochloride 1000mg Rosiglitazone maleate 4mg and metformin hydrochloride 1000mg	Added to the Additional List. FC January 2007 WITHDRAWN FROM THE MARKET October 2010

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
10.07.06 *SMC Report No. 281/06* PRODUCT UPDATE (abbreviated submission)	rosiglitazone / metformin 2mg/500mg, 2mg/1g, 4mg/1g tablets (Avandamet®) *GlaxoSmithKline UK Pharma* *In combination with a sulphonylurea as triple oral therapy in patients (particularly in overweight patients) who are unable to achieve sufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin*	Restricted use: rosiglitazone / metformin tablet (Avandamet®) is accepted for restricted use within NHS Scotland in combination with a sulphonylurea as triple oral therapy in patients (particularly in overweight patients) who are unable to achieve sufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin. Triple therapy should be initiated and monitored only by physicians experienced in the treatment of diabetes mellitus who will be able to identify and manage patients who might benefit. The combination formulations are not associated with increased costs compared to equivalent combinations of single drug formulations.	New formulation of a drug already included in the Formulary. For stable patients already established on the individual components. FC October 2007 WITHDRAWN FROM THE MARKET October 2010
08.03.04 *SMC Report No. 77/04* PRODUCT UPDATE (abbreviated submission)	rosiglitazone, metformin (Avandamet®) *GlaxoSmithKline UK Pharma* *Type 2 diabetes mellitus*	Accepted for use: rosiglitazone, metformin (Avandamet®) is accepted for use within NHS Scotland for the treatment of type 2 diabetes mellitus. It is used for overweight patients who are unable to achieve sufficient glycaemic control at their maximally tolerated doses of oral metformin alone and cannot be treated with a sulphonylurea in combination with metformin. This combination product costs the same as equivalent doses of the individual constituent preparations and offers a more convenient dosing regimen, though less flexible.	Added to the Additional List. FC January 2007 WITHDRAWN FROM THE MARKET October 2010
09.05.03 *SMC Report No. 45/03*	rosuvastatin (Crestor®) *AstraZeneca* *Reduction of low-density-lipoprotein-cholesterol (LDL-C)*	Accepted for use: rosuvastatin is a new HMG-CoA reductase inhibitor, with costs and efficacy in reducing low-density-lipoprotein-cholesterol (LDL-C) comparable to other statins. Its current licensed indications are more limited than some other statins.	Added to the Additional List, for Specialist use only. FC November 2005
10.10.11 *SMC Report No. 725/11*	rosuvastatin, 5mg, 10mg, 20mg, film-coated tablets (Crestor®) *AstraZeneca UK Ltd.* *Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors.*	NOT RECOMMENDED**:** rosuvastatin (Crestor®) is not recommended for use within NHS Scotland. Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors**.** In a randomised, placebo-controlled, double-blind, multi-centre study, treatment with rosuvastatin was associated with a significantly reduced risk of first cardiovascular event versus placebo in patient sub-groups deemed to be high-risk when assessed using the Framingham equation and the SCORE algorithm. The submitting company did not present sufficiently robust economic analysis to gain acceptance by SMC**.**	NOT RECOMMENDED
09.07.07 *SMC Report No. 289/06* RESUBMISSION	rotigotine 2mg/24 hours, 4mg/24 hours, 6mg/24 hours, 8mg/24 hours transdermal patch (Neupro®) *Schwarz Pharma Ltd* *Treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa)*	Accepted for use: rotigotine (Neupro®) is accepted for use within NHS Scotland for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa). Rotigotine was superior to placebo in two randomised controlled trials. However, in one active comparator study it was less effective than a non-ergolinic dopamine agonist comparator. Rotigotine transdermal patch offers an alternative non-ergolinic dopamine agonist at a lower cost in a formulation that does not have to be taken by mouth.	Added to the LJF as a Prescribing Note, Specialist Initiation FC April 2011

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13.08.07 *SMC Report No. 392/07*	rotigotine 2mg/24 hours, 4mg/24 hours, 6mg/24 hours, 8mg/24 hours transdermal patch (Neupro®) *Schwarz Pharma Ltd* *Treatment of the signs and symptoms of advanced idiopathic Parkinson's disease in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on-off" fluctuations)*	Restricted use: rotigotine (Neupro®) is accepted for restricted use within NHS Scotland for the treatment of the signs and symptoms of advanced idiopathic Parkinson's disease in combination with levodopa; i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on-off" fluctuations). Rotigotine increased the proportion of patients achieving □ 30% reduction in "off" time compared with placebo, but appeared to be less effective than another non-ergolinic dopamine agonist. Rotigotine trans-dermal patch offers an alternative non-ergolinic dopamine agonist at a lower cost in a formulation that does not have to be taken by mouth. It is restricted to patients where this route would facilitate treatment.	Added to the LJF as a Prescribing Note, Specialist Initiation FC April 2011
10.08.09 *SMC Report No. 548/09*	rotigotine, 1mg, 2mg and 3mg per 24 hours transdermal patch (Neupro®) *UCB Pharma Ltd* *Symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.*	Accepted for use: rotigotine (Neupro®) is accepted for use within NHS Scotland for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults. It should only be used in patients with a baseline score of 15 points or more on the International Restless Legs Scale (IRLS). Compared with placebo, rotigotine was associated with improvements on a patient-administered scale based on the core clinical features of the syndrome and on the incidence of periodic limb movements during time in bed. Other dopamine agonists licensed for use in RLS are available at a lower cost.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication. FC August 2010
10.11.08 *SMC Report No. 416/07* RESUBMISSION	rufinamide 100mg, 200mg and 400mg tablets (Inovelon®) *Eisai Limited* *Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients four years and older*	Restricted use: rufinamide (Inovelon®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients four years and older. Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. Rufinamide is restricted to use in patients who have failed treatment with or are intolerant of alternative traditional antiepileptic drugs.	Added to the Additional List. Patients should be seen to respond to treatment prior to transferring the prescribing to primary care. FC May 2009
03.07.12 *SMC Report No. 795/12* PRODUCT UPDATE (abbreviated submission)	rufinamide 40mg/mL oral suspension (Inovelon®) *Eisai Ltd* *Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older.*	Restricted use: rufinamide 40mg/mL oral suspension (Inovelon®) is accepted for restricted use within NHS Scotland as an adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older. SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs. Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. The oral suspension is bioequivalent to the tablets and provides an alternative formulation for patients who have difficulty swallowing. Depending on the dose it may be more expensive than the tablets but any overall budget impact is likely to be small.	Included on the Additional List for the indication in question. As an alternative formulation for patients who have difficulty swallowing. FC July 2012
08.03.10 *SMC Report No. 612/10* NON SUBMISSION	rupatadine (Rupafin®) *GlaxoSmithKline* *Symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and adolescents (over 12 years of age).*	NOT RECOMMENDED: rupatadine (Rupafin®) is not recommended for use within NHS Scotland for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and adolescents (over 12 years of age). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED

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08.04.13 *SMC Report No. 867/13* NON SUBMISSION	ruxolitinib (Jakavi®) 5mg, 15mg and 20mg Tablets *Novartis Pharmaceuticals UK Ltd* *Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.*	NOT RECOMMENDED: ruxolitinib (Jakavi®) is not recommended for use within NHS Scotland for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.10.08 *SMC Report No. 504/08* PRODUCT UPDATE (abbreviated submission)	salbutamol (as sulphate) 100 micrograms per dose as powder for inhalation (Salbulin® MDPI Novolizer) *Meda Pharmaceuticals Ltd* *Treatment in patients with reversible airways obstruction such as asthma for relief and prevention of asthma symptoms.*	Accepted for use: salbutamol (as sulphate) 100 micrograms per dose as powder for inhalation (Salbulin MDPI Novolizer) is accepted for use within NHS Scotland in patients with reversible airways obstruction such as asthma for relief and prevention of asthma symptoms. It may be used in patients in whom treatment with this short-acting beta agonist is appropriate and for whom delivery by a breath-activated dry powder inhaler device offers advantages over other delivery systems. It should be used to relieve asthma symptoms when they occur and to prevent symptoms in circumstances known by the patient to precipitate symptoms, for example prior to exercise or allergen exposure. It should be used for patients in whom a short-acting beta-agonist is appropriate and for whom a dry powder inhaler is an appropriate delivery device. It has a similar cost to other dry powder inhaled formulations of salbutamol.	Added to the LJF Respiratory section. FC October 2008
07.08.06 *SMC Report No. 292/06* PRODUCT UPDATE (abbreviated submission)	salmeterol 25micrograms inhaler (Serevent Evohaler®) *GlaxoSmithKline* *Regular symptomatic treatment of reversible airways obstruction in patients with asthma, including those with nocturnal asthma or chronic obstructive pulmonary disease.*	Accepted for use: salmeterol 25micrograms inhaler (Serevent Evohaler®) is accepted for use in NHS Scotland for the regular symptomatic treatment of reversible airways obstruction in patients with asthma, including those with nocturnal asthma or chronic obstructive pulmonary disease. It may also be used for the prevention of exercise-induced asthma. Where the use of this long-acting beta agonist by aerosol inhalation is appropriate, it offers a chlorofluorocarbon (CFC)-free option at no additional cost.	New formulation of a drug already included in the Formulary. FC October 2007
12.01.09 *SMC Report No. 450/08* RESUBMISSION	salmeterol/fluticasone 50/500 micrograms inhaler (Seretide 500 Accuhaler®) *GlaxoSmithKline* *Treatment of patients with chronic obstructive airway disease with a forced expiratory volume in 1 second (FEV_1) 50% to <60% predicted normal.*	NOT RECOMMENDED: salmeterol/fluticasone 50/500 micrograms inhaler (Seretide 500 Accuhaler®) is not recommended for use within NHS Scotland for the symptomatic treatment of patients with chronic obstructive airways disease (COPD) with a forced expiratory volume in 1 second (FEV_1) 50% to <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. While there was an improvement in lung function tests and a reduction in both moderate and severe exacerbations with salmeterol/fluticasone in comparison with placebo, there was no difference in mortality rate over 3 years. In addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
12.07.04 *SMC Report No. 108/04* PRODUCT UPDATE (abbreviated submission)	salmeterol xinafoate 25micrograms/ fluticasone propionate 50micrograms (Seretide 50 Evohaler®) *GlaxoSmithKline UK* *Asthma.*	Accepted for use: Seretide 50 Evohaler® is accepted for use within NHS Scotland for the regular treatment of asthma where use of a combination of the long-acting beta agonist salmeterol and the inhaled corticosteroid fluticasone is appropriate for a child aged 4-12 years. The acquisition cost of the combination product is less than for the individual components given by aerosol inhalation and for the combination given by Accuhaler®.	Added to the LJF for Children as a combination product for children with moderate to severe asthma who are stable on the individual products. FC April 2005
08.06.09 *SMC Report No. 558/09* NON SUBMISSION	sapropterin (Kuvan®) 100mg soluble tablets *Merck Serono* Treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with phenylketonuria (PKU) and for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with tetrahydrobiopterin (BH4) deficiency.	NOT RECOMMENDED: sapropterin (Kuvan®) is not recommended for use within NHSScotland for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with phenylketonuria (PKU) and for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with tetrahydrobiopterin (BH4) deficiency. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.03.10 *SMC Report No. 603/10*	saxagliptin, 5mg film-coated tablet (Onglyza®) *Bristol-Myers Squibb Pharmaceuticals Ltd* *As add-on combination therapy, saxagliptin is indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control.*	Restricted use: saxagliptin (Onglyza®) is accepted for restricted use within NHS Scotland in adult patients with type 2 diabetes mellitus as add-on combination therapy with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control. It is restricted to use in patients only when the addition of sulphonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of HbA1c, is comparable to another dipeptidyl peptidase-4 inhibitor. It appears to have minimal effect on body weight. Saxagliptin is also licensed for use in combination with sulphonylureas or thiazolidinedione drugs for the treatment of type 2 diabetes. The manufacturer's submission related only to the use of saxagliptin in combination with metformin. SMC cannot recommend the use of saxagliptin in combination with sulphonylureas or thiazolidinediones.	Approved in principle for addition to the LJF as a prescribing note. Diabetes section to be reviewed by the Diabetes Working Group and exact place in therapy to be decided. FC May 2010
13.02.12 *SMC Report No. 772/12* NON SUBMISSION	saxagliptin (Onglyza®) 2.5 mg and 5 mg film-coated tablets *AstraZeneca* *Adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.*	NOT RECOMMENDED: saxagliptin (Onglyza®) is not recommended for use within NHS Scotland for the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. The holder of the marketing authorisation has not made a submission to SMC regarding this product in combination with insulin in type 2 diabetes mellitus. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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09.12.13 *SMC Report No. 918/13*	saxagliptin 2.5mg and 5mg film-coated tablets (Onglyza®) *Bristol-Myers Squibb/AstraZeneca* *In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.*	Restricted use: saxagliptin (Onglyza®) is accepted for restricted use within NHS Scotland in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. SMC restriction: as an alternative dipeptidyl peptidase-4 inhibitor option. Treatment with saxagliptin reduces glycosylated haemoglobin, HbA1c, levels significantly more than placebo when used in combination with metformin and a sulphonylurea. Indirect comparisons demonstrated similar efficacy to other dipeptidyl peptidase-4 inhibitors.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is sitagliptin. FC January 2014
10.03.14 *SMC Report No. 958/14* NON SUBMISSION	saxagliptin (Onglyza®) 2.5mg & 5mg film-coated tablets *Bristol Myers Squibb / Astra Zeneca* *Monotherapy in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.*	NOT RECOMMENDED: saxagliptin (Onglyza®) is not recommended for use within NHS Scotland as monotherapy in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.06.13 *SMC Report No. 870/13* PRODUCT UPDATE (abbreviated submission)	saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg tablets (Komboglyze®) *Bristol Myers Squibb / AstraZeneca* *Adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets.*	Restricted use: saxagliptan plus metformin (Komboglyze®) is accepted for restricted use within NHS Scotland as adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets. SMC restriction: use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate. Saxagliptin represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of HbA1c, is comparable to another dipeptidyl peptidase-4 inhibitor. It appears to have minimal effect on body weight. Saxagliptin/metformin is also licensed for use in combination with insulin for the treatment of type 2 diabetes. The manufacturer's submission related only to the use of saxagliptin and metformin in combination therefore SMC cannot recommend the use of saxagliptin/metformin in combination with insulin.	**Not included** in the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is sitagliptin. Combination product of sitagliptin and metformin are included as a prescribing note. FC June 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.01.14 *SMC Report No. 929/13* PRODUCT UPDATE (abbreviated submission)	saxagliptin plus metformin, 2.5mg / 850mg and 2.5mg / 1000mg film-coated tablets (Komboglyze®) *Bristol-Myers Squibb / AstraZeneca* *In combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus when the maximally tolerated dose of both metformin and the sulphonylurea does not provide adequate glycaemic control.*	Accepted for use: saxagliptin plus metformin (Komboglyze®) is accepted for use within NHS Scotland in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus when the maximally tolerated dose of both metformin and the sulphonylurea does not provide adequate glycaemic control. For patients in whom triple combination therapy with metformin, a sulphonylurea and saxagliptin is appropriate, saxagliptin/metformin has the potential to reduce the pill burden at a lower cost.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is sitagliptin. Combination product of sitagliptin and metformin are included as a prescribing note. FC January 2014
10.11.03 *SMC Report No. 68/03*	sertraline (Lustral®) *Pfizer Ltd* *Post-traumatic stress disorder (PTSD) in females.*	NOT RECOMMENDED: sertraline has demonstrated some benefit in treating post-traumatic stress disorder (PTSD) in two of four 12-week double blind treatment studies, and in extension studies for up to 64 weeks. The product licence restricts its use to women only; a narrower indication than for the other drug currently licensed for treating PTSD, and against which no comparative trials have been conducted. The manufacturer submitted no evidence to demonstrate the cost effectiveness of their drug.	NOT RECOMMENDED
10.12.07 *SMC Report No. 423/07*	sevelamer hydrochloride, 800mg tablets (Renagel®) *Genzyme Therapeutics Ltd* *Control of hyperphosphataemia in adult patients receiving peritoneal dialysis.*	NOT RECOMMENDED: sevelamer (Renagel®) is not recommended for use within NHS Scotland for control of hyperphosphataemia in adult patients receiving peritoneal dialysis. It was non-inferior to a calcium-based phosphate binder in reducing serum phosphate and was associated with a lower rate of hypercalcaemia. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
11.04.11 *SMC Report No. 641/10* *RESUBMISSION* PRODUCT UPDATE (abbreviated submission)	sevelamer carbonate, 800mg film-coated tablets and 2.4g of anhydrous powder for oral suspension (Renvela®) *Genzyme Therapeutics Limited* *Control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.*	Restricted Use: sevelamer carbonate (Renvela®) is accepted for restricted use within NHS Scotland. Indication under review: for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. SMC restriction: the second-line management of hyperphosphataemia in adult patients receiving haemodialysis. Sevelamer carbonate has been shown to be therapeutically equivalent to sevelamer hydrochloride in reducing serum phosphorus in patients with chronic kidney disease on haemodialysis. For patients in whom sevelamer hydrochloride is an appropriate choice of phosphate binder, the carbonate salt provides an alternative at no additional cost. Sevelamer carbonate is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus ≥ 1.78 mmol/L. As the manufacturer's submission related only to the control of hyperphosphataemia in adult patients receiving haemodialysis SMC cannot recommend the use of sevelamer carbonate in pre-dialysis patients or in peritoneal dialysis patients.	Added to the Additional List, for Specialist Initiation in haemodialysis patients FC April 2011
13.02.06 *SMC Report No. 235/06*	sildenafil citrate 20mg tablets (Revatio®) *Pfizer* *Treatment of patients with pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity.*	Restricted use: sildenafil citrate (Revatio®) is accepted for restricted use within NHS Scotland for the treatment of patients with pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity. This is an orphan indication for sildenafil with limited clinical evidence from short-term clinical trials. It is restricted to initiation by specialists working in the Scottish Pulmonary Vascular Unit and by physicians experienced in the management of pulmonary vascular disease.	Added to the Additional List, only if initiated by specialists working in the Scottish Pulmonary Vascular Unit. FC October 2007

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08.02.10 *SMC Report No. 596/10*	sildenafil, 20mg (as citrate) tablets (Revatio®) *Pfizer Ltd* *Treatment of patients with pulmonary arterial hypertension (PAH) classified as WHO functional class (FC) II, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.*	Restricted use: sildenafil citrate (Revatio®) is accepted for restricted use within NHS Scotland for treatment of patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. It is restricted to initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists. This is an orphan indication for sildenafil with limited clinical evidence from post-hoc analysis of a short-term clinical trial.	Added to the Additional List, only if initiated by specialists working in the Scottish Pulmonary Vascular Unit. FC May 2011
07.03.11 *SMC Report No. 688/11* PRODUCT UPDATE (abbreviated submission)	sildenafil citrate 0.8mg/mL solution for injection (Revatio®) *Pfizer UK* *Treatment of patients with pulmonary arterial hypertension who are currently prescribed oral sildenafil and who are temporarily unable to take oral medicine, but are otherwise clinically and haemodynamically stable.*	Restricted use: sildenafil citrate 0.8mg/mL injection (Revatio®) is accepted for restricted use within NHS Scotland. Indication under review: for the treatment of patients with pulmonary arterial hypertension who are currently prescribed oral sildenafil and who are temporarily unable to take oral medicine, but are otherwise clinically and haemodynamically stable. SMC restriction: restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service. Oral sildenafil is indicated for treatment of patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. SMC has previously accepted oral sildenafil in this orphan indication. The intravenous formulation is significantly more expensive than the oral preparation but it is intended only for short-term use (the estimated average duration of intravenous treatment is three days).	Added to the Additional List, on the advice of a specialist in the Scottish Pulmonary Vascular Unit. FC March 2011
10.12.12 *SMC Report No. 809/12* PRODUCT UPDATE (abbreviated submission)	sildenafil (as citrate) 20mg film-coated tablets and 10mg/mL powder for oral solution (Revatio®) *Pfizer UK* *Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.*	Restricted use: sildenafil (Revatio®) is accepted for restricted use within NHS Scotland for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease SMC restriction: restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service. SMC has previously accepted this orphan indication for oral sildenafil for restricted use within NHS Scotland for the treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. Sildenafil is listed in the British National Formulary for Children 2011-2012 for use in pulmonary hypertension after cardiac surgery, weaning from nitric oxide, idiopathic pulmonary arterial hypertension, persistent pulmonary hypertension of the newborn.	**Included** on the Additional List for the indication in question, only if initiated by specialist working in the Scottish Pulmonary Vascular Unit and the Scottish Adult Congenital Cardiac Service. FC December 2012

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08.10.07 *SMC Report No. 408/07*	sitagliptin 100mg tablets (Januvia®) *Merck, Sharpe & Dohme Limited* *Treatment of patients with type 2 diabetes mellitus to improve glycaemic control in combination with metformin when diet and exercise, plus metformin, do not provide adequate glycaemic control.*	Restricted use: sitagliptin (Januvia®) is accepted for restricted use within NHS Scotland for treatment of patients with type 2 diabetes mellitus to improve glycaemic control in combination with metformin when diet and exercise, plus metformin, do not provide adequate glycaemic control. It should be restricted to use in patients only when the addition of sulphonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of HbA1c, is similar to sulphonylurea and thiazolidinedione drugs added at this stage in therapy. It appears to have minimal effects on body weight.	Added to the LJF as a prescribing note as an alternative to thiazolidinediones in diabetic patients where thiazolidinediones are not tolerated or are contraindicated. To be initiated by clinicians (primary or secondary care) with a special interest in diabetes. FC March 2008
13.10.08 *SMC Report No. 505/08*	sitagliptin, 100mg tablet (Januvia®) *Merck Sharp and Dohme Limited* *Treatment of patients with type 2 diabetes mellitus to improve glycaemic control in combination with a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance; or in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.*	Accepted for use: sitagliptin (Januvia®) is accepted for use within NHS Scotland for patients with type 2 diabetes mellitus to improve glycaemic control in combination with a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance; or in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control. When added to a sulphonylurea with or without metformin, sitagliptin had a modest beneficial effect on glycated haemoglobin (HbA1c) levels. Sitagliptin is also licensed for use in combination with thiazolidinedione drugs. The manufacturer's submission related only to the use of sitagliptin in combination with sulphonylureas with or without metformin. SMC cannot recommend the use of sitagliptin in combination with thiazolidinediones.	Added to the LJF as first choice gliptin for all SMC approved indications. FC November 2010
12.07.10 *SMC Report No: 607/10*	sitagliptin, 100mg film-coated tablet (Januvia®) *Merck Sharp & Dohme Ltd* *Type 2 diabetes mellitus as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.*	Restricted use: sitagliptin (Januvia®) is accepted for restricted use within NHS Scotland. Licensed indaication under review: as monotherapy, to improve glycaemic control in patients with type 2 diabetes mellitus who are inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. SMC restriction: to patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance. Sitagliptin met the pre-defined efficacy criterion for non-inferiority versus metformin in a study of treatment naïve patients. It appears to have minimal effect on body weight. The health economic case was demonstrated only for a sub-population of patients within the licensed indication. The licensed indication for sitagliptin has also recently been extended to include use in triple combination therapy with metformin plus thiazolidinediones and use as add-on therapy to insulin. The manufacturer's submission related only to the use of sitagliptin as monotherapy Therefore SMC cannot recommend the use of sitagliptin in combination with metformin plus thiazolidinediones or as add-on therapy to insulin.	Added to the LJF as first choice gliptin for all SMC approved indications. FC November 2010

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10.05.10 *SMC Report No: 492/08* PRODUCT UPDATE (abbreviated submission)	sitagliptin 50 mg and metformin hydrochloride 1000 mg tablets (Janumet® 50/1000) *Merck Sharp and Dohme Ltd* *Type 2 diabetes mellitus.*	Restricted use: sitagliptin 50 mg and metformin hydrochloride 1000 mg (Janumet® 50/1000): is accepted for restricted use within NHS Scotland. Licensed indication under review: as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of sitagliptin and metformin. SMC restriction: restricted to use in patients for whom a combination of sitagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate. Sitagliptin represents an alternative to other agents such as thiazolidinediones. Efficacy of sitagliptin when added to metformin, as assessed by measurement of HbA1c, is similar to sulphonylurea and thiazolidinedione drugs added at this stage in therapy. It appears to have minimal effects on body weight.	Added to the LJF as a prescribing note. Diabetes section to be reviewed by the Diabetes Working Group. FC May 2010
09.08.10 *SMC Report No. 627/10* PRODUCT UPDATE (abbreviated submission)	sitagliptin 50mg plus metformin hydrochloride 1000mg film-coated tablet (Janumet® 50/1000) *MSD Ltd* *In combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.*	Accepted for use: sitagliptin plus metformin (Janumet® 50/1000): is accepted for use within NHS Scotland. Licensed indication under review: In combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. For patients in whom triple combination therapy with metformin, a sulphonylurea and sitagliptin is appropriate it has the potential to reduce the pill burden at no additional cost. When added to a sulphonylurea with metformin, sitagliptin has shown a modest effect on glycated haemoglobin (HbA1c) levels. Note that a lower dose of the sulphonylurea may be required to reduce the risk of hypoglycaemia. Sitagliptin/metformin is also licensed for use in triple combination therapy with a thiazolidinedione or as add-on to insulin. The manufacturer's submission related only to the use of sitagliptin/metformin in combination with a sulphonylurea, therefore SMC cannot recommend the use of sitagliptin/metformin in triple therapy with either a thiazolidinedione or insulin.	Added to the LJF as a prescribing note. FC November 2010
07.05.07 *SMC Report No. 360/07*	sitaxentan 100mg tablets (Thelin®) *Encysive (UK) Ltd* *Treatment of patients with pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity.*	Restricted use: sitaxentan sodium (Thelin®) is accepted for restricted use within NHS Scotland for the treatment of patients with pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and in pulmonary hypertension associated with connective tissue disease. Data suggest that sitaxentan 100mg daily has a benefit/risk ratio comparable to the other licensed endothelin receptor antagonist. Non-inferiority has not been formally demonstrated as sitaxentan is an orphan drug with limited clinical evidence. Where an endothelin receptor antagonist is indicated, sitaxentan provides an alternative. It is restricted to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit.	Added to the Additional List, only if initiated by specialists working in the Scottish Pulmonary Vascular Unit. FC April 2008
10.09.07 *SMC Report No. 246/06* RESUBMISSION	sodium oxybate 500mg/mL oral solution (Xyrem®) *UCB Pharma Ltd* *Treatment of cataplexy in adult patients with narcolepsy.*	NOT RECOMMENDED: sodium oxybate (Xyrem®) is not recommended for use within NHS Scotland for the treatment of cataplexy in adult patients with narcolepsy. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED

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11.11.13 *SMC Report No. 914/13* PRODUCT UPDATE (abbreviated submission)	sodium phenylbutyrate granules 483mg/g (Pheburane®) *Lucane Pharma* *Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.*	Accepted for use: sodium phenylbutyrate granules (Pheburane®) are accepted for use within NHS Scotland as adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. It is indicated in all patients with neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonaemic encephalopathy. Sodium phenylbutyrate granules (Pheburane®) provide an alternative to sodium phenylbutyrate tablets at no additional cost but are more expensive than an existing brand of sodium phenylbutyrate granules.	**Included** on the Additional List, for the indication in question. FC November 2013
09.06.14 *SMC Report No. 964/14*	sofosbuvir 400mg tablet (Sovaldi®) *Gilead Sciences Ltd.* *In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.*	Restricted use: sofosbuvir (Sovaldi®) is accepted for restricted use within NHS Scotland in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. SMC restriction: Sofosbuvir is accepted for use in patients with genotypes 1 to 6. Use in treatment-naive patients with genotype 2 is restricted to those who are ineligible for, or are unable to tolerate, peginterferon alfa. Use of the 24-week interferon-free regimen of sofosbuvir in combination with ribavirin in patients with genotype 3 is restricted to those who are ineligible for, or are unable to tolerate, peginterferon alfa. Sofosbuvir in combination with ribavirin, or peginterferon plus ribavirin, produced sustained virological suppression in patients with all genotypes of hepatitis C. It is the first medicine licensed for use in interferon-free regimens and may be associated with improved tolerability compared to standard interferon-based regimens. No clinical or economic data were presented for treatment-experienced patients with genotype 1.	**Included** on the Additional List, for Specialist Use only, for the indication in question. Prescribing of sofosbuvir is to be in line with the SMC recommendation and the UK Consensus Guidelines. FC July 2014
07.11.05 *SMC Report No. 129/04* RESUBMISSION	solifenacin succinate 5mg, 10mg (Vesicare®) *Yamanouchi* *Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.*	Accepted for use: solifenacin succinate (Vesicare®) is accepted for use within NHS Scotland for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Solifenacin is effective in reducing symptoms associated with overactive bladder, including frequency, urgency and incontinence. It is associated with adverse events typical of antimuscarinic agents used in this condition. There are cheaper antimuscarinics available that would normally be used as first-line agents.	Added to the LJF as replacement for tolterodine. FC October 2008
10.03.14 *SMC Report No. 945/14* PRODUCT UPDATE (abbreviated submission)	solifenacin succinate plus tamsulosin hydrochloride 6mg / 0.4mg modified release tablet (Vesomni®) *Astellas Pharma Ltd* *For the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.*	Accepted for use: solifenacin succinate plus tamsulosin hydrochloride 6mg / 0.4mg modified release tablet (Vesomni®) is accepted for use within NHS Scotland for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy. In patients for whom concomitant use of solifenacin succinate and tamsulosin hydrochloride is appropriate, Vesomni® allows administration of a single tablet at a lower cost compared to the individual components administered separately.	**Not included** on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choices are oxybutynin or solifenacin and tamsulosin. FC February 2014

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
13.03.06 *SMC Report No. 240/06* PRODUCT UPDATE (abbreviated submission)	somatropin (Genotropin®) injection *Pfizer Limited* *Treatment of growth disturbance.*	Restricted use: somatropin (Genotropin®) injection is accepted for restricted use within NHS Scotland for the treatment of growth disturbance (current height Standard Deviation Score (SDS) <-2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 Standard Deviations, who failed to show catch-up growth (height velocity SDS < 0 during the last year) by 4 years of age or later. Treatment should be initiated and monitored by a paediatrician with expertise in managing childhood growth disorders and growth hormone therapy.	Added to the LJF for Children as first choice - to be initiated by Specialists only. Genotropin® is one of the branded preparations of somatropin already included in the LJF for Children and a shared care protocol is currently in place. FC May 2006
12.06.06 *SMC Report No. 260/06* PRODUCT UPDATE (abbreviated submission)	somatropin (Norditropin SimpleXx®) *Novo Nordisk* *Treatment of growth disturbance (current height standard deviation score (SDS) <-2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 standard deviations, who failed to show catch-up growth (height velocity SDS < 0 during the last year) by 4 years of age or later.*	Restricted use: somatropin (Norditropin SimpleXx®) injection is accepted for restricted use within NHS Scotland for the treatment of growth disturbance (current height standard deviation score (SDS) <-2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 standard deviations, who failed to show catch-up growth (height velocity SDS < 0 during the last year) by 4 years of age or later. Treatment should be initiated and monitored by a paediatrician with expertise in managing childhood growth disorders and growth hormone therapy.	Extension to licence of a drug already included in the Formulary.
08.02.10 *SMC Report No. 598/10*	somatropin for injection, 5mg/mL vial of powder and solvent for solution for subcutaneous injection and 3.3mg/mL and 6.7mg/mL penfill cartridge of solution for subcutaneous injection (Omnitrope®) *Sandoz Ltd* *Infants, children and adolescents* *Growth disturbance due to insufficient secretion of growth hormone (GH), associated with Turner syndrome (TS), associated with chronic renal insufficiency (CRI)* *Prader–Willi syndrome (PWS),.* *Adults* *Replacement therapy in adults with pronounced GH deficiency.*	Accepted for use: somatropin (Omnitrope®) is accepted for use within NHS Scotland for: Infants, children and adolescents -Growth disturbance due to insufficient secretion of growth hormone (GH) -Growth disturbance associated with Turner syndrome -Growth disturbance associated with chronic renal insufficiency -Growth disturbance (current height standard deviation score (SDS) <–2.5 and parental adjusted SDS <–1) in short children/adolescents born small for gestational age, with a birth weight and/or length below -2 standard deviation (SD), who failed to show catch-up growth (height velocity SDS <0 during the last year) by four years of age or later -Prader-Willi syndrome (PWS) disturbance due to insufficient secretion of growth hormone, for improvement of growth and body composition. The diagnosis of PWS should be confirmed by appropriate genetic testing. Adults -Replacement therapy in adults with pronounced GH deficiency. Patients with severe GH deficiency in adulthood are defined as patients with known hypothalamic-pituitary pathology and at least one known deficiency of a pituitary hormone not being prolactin. These patients should undergo a single dynamic test in order to diagnose or exclude a GH deficiency. In patients with childhood onset isolated GH deficiency (no evidence of hypothalamic –pituitary disease or cranial irradiation), two dynamic tests should be recommended, except for those who have low insulin-like growth factor 1 (IGF-1) concentrations (SDS <-2), who may be considered for one test. The cut-off point of the dynamic test should be strict. Somatropin (Omnitrope®) is a biosimilar product and has demonstrated equivalency in terms of efficacy and safety to a reference recombinant human growth hormone (somatropin (Genotropin®)). The British National Formulary advises that it is good practice to use the brand name when prescribing biological medicinal products.	Added to the Additional List FC July 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.11.11 *SMC Report No. 737/11* PRODUCT UPDATE (abbreviated submission)	somatropin 5.83mg/ml and 8mg/ml solution for injection (Saizen®) *Merck Serono Ltd* *Children and adolescents:* *- Growth failure in children caused by decreased or absent secretion of endogenous growth hormone.* *- Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis.* *- Growth failure in prepubertal children due to chronic renal failure (CRF).* *- Growth disturbance (current height SDS <-2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later.* *Adults:* *- Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency.*	Accepted for use: somatropin solution for injection (Saizen®) is accepted for use in NHS Scotland. Children and adolescents: - Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. - Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis. - Growth failure in prepubertal children due to chronic renal failure (CRF). - Growth disturbance (current height SDS <-2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later. Adults: - Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency. Patients must also fulfil the following criteria: - Childhood Onset: Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their growth hormone deficiency confirmed before replacement therapy with Saizen is started. - Adult Onset: Patients must have growth hormone deficiency as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin. This new formulation has been shown to be bioequivalent to the previously available freeze-dried formulation and is available at an equivalent cost. It is in a ready to use cartridge and does not require reconstitution.	Added to the Additional List FC March 2012
13.11.06 *SMC Report No. 321/06*	sorafenib 200mg tablets (Nexavar®) *Bayer Plc* *Treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alfa or interleukin-2 based therapy or are considered unsuitable for such therapy.*	NOT RECOMMENDED: sorafenib (Nexavar®) is not recommended for use within NHS Scotland for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alfa or interleukin-2 based therapy or are considered unsuitable for such therapy. Sorafenib has been compared with best supportive care and has been shown to increase progression-free survival, though the impact on overall survival is uncertain. The cost effectiveness of sorafenib has not been demonstrated.	NOT RECOMMENDED
17.01.11 *SMC Report No. 482/08* RESUBMISSION	sorafenib, 200mg tablets (Nexavar®) *Bayer Schering Pharma* *Treatment of hepatocellular carcinoma.*	NOT RECOMMENDED: sorafenib (Nexavar®) is not recommended for use within NHS Scotland for the treatment of hepatocellular carcinoma. Indication under review: the treatment of hepatocellular carcinoma. In one study in patients with advanced hepatocellular carcinoma, sorafenib was superior to placebo in terms of overall survival, but not for the time to symptomatic progression. The manufacturer did not present a sufficiently robust economic analysis and in addition, the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED.

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
14.01.08 *SMC Report No. 367/07* RESUBMISSION	standardised allergen extract of grass pollen from Timothy (*Phleum pratense*) 75,000 SQ-T per oral lyophilisate (Grazax®) *ALK-Abelló Ltd* *Treatment of grass pollen induced rhinitis and conjunctivitis in adult patients with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.*	NOT RECOMMENDED: Standardised allergen extract of grass pollen 75,000 per oral lyophilisate (Grazax®) is not recommended for use within NHS Scotland for the treatment of grass pollen induced rhinitis and conjunctivitis in adult patients with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen. Although modest clinical benefit has been shown, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.01.09 *SMC Report No. 524/08*	stiripentol, 250mg hard capsules and 250mg powder for oral suspension in sachet and 500mg hard capsules and 500mg powder for oral suspension in sachet (Diacomit®) *Biocodex* *In conjunction with clobazam and valproate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate.*	NOT RECOMMENDED: stiripentol (Diacomit®) is not recommended for use within NHS Scotland for use in conjunction with clobazam and valproate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate. The number of responders with >50% reduction in the number of clonic (or tonic-clonic) seizures was significantly greater in SMEI patients receiving adjunctive stiripentol than in patients receiving placebo. The product did not gain acceptance by SMC as the manufacturer did not present a formal economic evaluation.	NOT RECOMMENDED
05.08.05 *SMC Report No. 178/05*	strontium ranelate 2g granules for oral suspension (Protelos®) *Servier laboratories Limited* *Postmenopausal osteoporosis.*	Restricted use: strontium ranelate (Protelos®) is accepted for restricted use within NHS Scotland for the treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures when bisphosphonates are contra-indicated or not tolerated and then only in women aged over 75 with a previous fracture and T-score < -2.4 or other women at equivalent high risk. In the trial population of postmenopausal women, strontium ranelate reduced the risk of developing a vertebral fracture by 41%. In women ≥ 74 years with a femoral neck Bone Mineral Density (BMD) T-score < -2.4 the risk of hip fractures was reduced by 36%. However equivalent cost effectiveness to bisphosphonate therapy has not been demonstrated.	Added to the Formulary as second choice in combination with Adcal-D_3® for the treatment of postmenopausal osteoporosis for women intolerant of bisphosphonates or where there are contraindications, e.g. oesophageal stricture. FC November 2005
08.10.12 *SMC Report No. 816/12* NON SUBMISSION	strontium ranelate (Protelos®) 2g granules for oral suspension *Servier Laboratories Limited* *Treatment of osteoporosis in men at increased risk of fracture.*	NOT RECOMMENDED: strontium ranelate (Protelos®) is not recommended for use within NHS Scotland for the treatment of osteoporosis in men at increased risk of fracture. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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09.02.09 *SMC Report No. 527/09*	sugammadex 100mg/ml solution for injection (Bridion®) *Schering-Plough* *Immediate reversal of rocuronium-induced neuromuscular blockade.*	Accepted for use: sugammadex (Bridion®) is accepted for restricted use within NHS Scotland for the immediate reversal of rocuronium-induced neuromuscular blockade. Sugammadex, when administered after rocuronium or vecuronium, has been shown to provide more rapid reversal of neuromuscular blockade than an anticholinesterase comparator and, when administered with rocuronium in the rapid sequence induction setting, gave a faster mean recovery time than using a depolarising neuromuscular blocking comparator. Sugammadex is accepted for restricted use in the immediate reversal of rocuronium-induced neuromuscular blockade in adults only. Sugammadex is not recommended for the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults, children and adolescents as the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	Added to Additional List, Specialist Use only. FC August 2009
11.03.13 *SMC Report No. 527/09* RESUBMISSION	sugammadex 100mg/mL (1mL, 2mL, 5mL) solution for injection (Bridion®) *Merck, Sharp & Dohme Limited* *For the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults and rocuronium in children and adolescents.*	Restricted use: sugammadex (Bridion®) is accepted for restricted use within NHS Scotland for the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults and rocuronium in children and adolescents. Indication under review: Reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents. This resubmission is for the part of the indication relating to routine reversal of neuromuscular blockade. SMC restriction: only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/chest surgery) or where prompt reversal of neuromuscular block is required. Sugammadex, when administered after rocuronium or vecuronium, has been shown to provide more rapid reversal of moderate and profound neuromuscular blockade than an anti-cholinesterase comparator. Sugammadex is significantly more expensive than conventional treatments used to reverse neuromuscular blockade.	**Not included** on the LJF because do not support the formulary inclusion. Sugammadex is recommended in Lothian for immediate reversal of rocuronium-induced neuromuscular blockade only. FC June 2013
11.10.04 *SMC Report No. 127/04* PRODUCT UPDATE (abbreviated submission)	sumatriptan succinate 50mg and 100mg tablets (Imigran Radis®) *GlaxoSmithKline UK Pharmaceuticals* *Acute relief of migraine attacks, with or without aura, provided there is a clear diagnosis of migraine.*	Accepted for use: Imigran Radis® film-coated tablets are accepted for use within NHS Scotland for acute relief of migraine attacks, with or without aura, provided there is a clear diagnosis of migraine. They offer a fast disintegrating oral formulation of sumatriptan succinate. No increased cost is associated with this product compared to prescribing conventional Imigran® tablets.	New formulation of a drug already included in the Formulary.
March 2009 *NICE MTA 169* *Supersedes SMC Report No. 384/07*	sunitinib 12.5mg, 25mg, 50mg capsules (Sutent®) *Pfizer Ltd* *Treatment of advanced and/or metastatic renal cell carcinoma (MRCC).*	Sunitinib is recommended as a first-line treatment option for people with advanced and/or metastatic renal cell carcinoma who are suitable for immunotherapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.	Added to the Additional List, for Specialist Use only. FC July 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.11.09 *SMC Report No. 275/06* RESUBMISSION Patient Access Scheme	sunitinib 50mg capsule (Sutent®) *Pfizer* *Treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance.*	Accepted for use: Sunitinib (Sutent®) is accepted for use within NHS Scotland for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesilate treatment due to resistance or intolerance. Sunitinib compared with placebo delayed tumour progression by approximately five months. Treatment with sunitinib should not be continued if there is evidence of unacceptable toxicity or progression of disease. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sunitinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist Use only FC July 2010
12.02.07 *SMC Report No. 343/07*	sunitinib 50mg capsule (Sutent®) *Pfizer* *Treatment of advanced and/or metastatic renal cell carcinoma after failure of interferon-alpha or interleukin-2 therapy.*	NOT RECOMMENDED: sunitinib (Sutent®) is not recommended for use within NHS Scotland for the treatment of advanced and/or metastatic renal cell carcinoma after failure of interferon-alpha or interleukin-2 therapy. In uncontrolled trials, sunitinib has been associated with tumour responses in patients who have metastatic renal cell cancer. However, the economic case has not been demonstrated.	NOT RECOMMENDED
09.05.11 *SMC Report No. 698/11* Patient Access Scheme	sunitinib 12.5mg, 25mg, 37.5mg, 50mg hard capsules (Sutent®) *Pfizer Limited* *Treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults. Experience with sunitinib as first-line treatment is limited.*	Accepted for use: sunitinib (Sutent®) is accepted for use within NHS Scotland. Indication under review: Treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults. Treatment with sunitinib improved progression free survival compared with placebo in patients with well-differentiated neuroendocrine carcinoma of the pancreas who were receiving best supportive care, including somatostatin analogues if required for symptomatic control. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sunitinib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	Added to the Additional List, for Specialist use only. FC August 2011
09.05.05 *SMC Report No. 168/05*	TachoSil® sponge (9.5cm x 4.8cm) containing fibrinogen 5.5mg and thrombin 2iu per cm^2 *Nycomed* *Haemostasis in liver surgery*	Accepted for use: TachoSil® is accepted for use within NHS Scotland for the improvement of haemostasis in liver surgery where standard techniques are insufficient.	Added to the Additional List, for Specialist Use only FC August 2005
12.02.07 *SMC Report No. 344/07*	TachoSil® medicated sponge *Nycomed* *Supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient.*	Accepted for use: TachoSil® medicated sponge is accepted for use within NHS Scotland for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient. In addition to the previous SMC advice for TachoSil® use in liver surgery the economic case for renal surgery has also now been demonstrated.	New indication for a drug already included in Formulary. FC April 2008
12.02.07 *SMC Report No. 346/07*	tacrolimus, 5mg/ml concentrate for infusion and 0.5mg, 1mg, 5mg hard capsules (Prograf®) *Astellas Pharma Ltd* *Prophylaxis of transplant rejection in heart allograft recipients.*	Restricted use: tacrolimus (Prograf®) is accepted for restricted use within NHS Scotland for the prophylaxis of transplant rejection in heart allograft recipients. It has shown comparable efficacy to ciclosporin-based regimens in prevention of acute rejection. It is restricted to use in patients where ciclosporin is not suitable.	Added to the Additional List, if initiated by specialists working in Heart Transplantation. Shared Care Protocol for use in Kidney and Liver transplants. FC December 2008

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
04.10.02 *SMC Report No. 12/02*	tacrolimus ointment 0.1% and 0.03% (Protopic®) *Fujisawa* *Atopic dermatitis.*	Restricted use: tacrolimus offers a treatment option for adults with atopic dermatitis intolerant of or unresponsive to conventional treatments, and for children aged 2 years or over who are unresponsive to conventional topical therapies. It is a potent immunosuppressant which can be absorbed systemically following topical application, and there are unresolved concerns about possible adverse effects arising from this. Its use should therefore be considered prior to oral therapy when it is deemed that other appropriate options for topical therapy have been exhausted. Its use should be initiated and supervised by dermatologists within secondary care who have experience of treating atopic dermatitis using immunomodulatory therapy. In order to facilitate future investigation of long-term effects of the use of tacrolimus ointment, it is advised that a register of recipients should be established and maintained.	Approved for use - added to the Formulary as third line treatment of severe atopic dermatitis. FC August 2005 FC decision remains unchanged. FC April 2013
10.09.07 *SMC Report No. 402/07* PRODUCT UPDATE (abbreviated submission)	tacrolimus 0.5mg, 1mg, 5mg prolonged-release capsule (Advagraf®) *Astellas Pharma* *Prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patient.*	Accepted for use: tacrolimus prolonged-release capsule (Advagraf®) is accepted for use within NHS Scotland for prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. It is suitable for use by patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy. It has similar costs per equivalent dose to the tacrolimus immediate release capsule.	New formulation of a drug already included in the Formulary. FC October 2007
12.04.10 *SMC Report No. 608/10*	tacrolimus 0.03% ointment (Protopic®) *Astellas Pharma Ltd* *For maintenance treatment of moderate to severe atopic dermatitis in children (aged 2 to15 years) for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).* *Tacrolimus ointment should be by doctors with a specialist interest and experience in treating atopic dermatitis using immunomodulatory therapy.*	Restricted use: tacrolimus 0.03% ointment (Protopic®) is accepted for restricted use within NHS Scotland. Licensed indication under review: for maintenance treatment of moderate to severe atopic dermatitis in children (aged 2 to15 years) for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected). SMC Restriction: Use is restricted to initiation by doctors with a specialist interest and experience in treating atopic dermatitis using immunomodulatory therapy (this can include General Practitioners. Twice weekly maintenance therapy with tacrolimus ointment resulted in reduced disease exacerbations when compared to intermittent use only to treat disease exacerbations.	Included on the LJF for the indication in question. The SCP will be amended to include maintenance treatment. FC April 2013

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
12.04.10 *SMC Report No. 609/10*	tacrolimus 0.1% ointment (Protopic®) *Astellas Pharma Ltd* *For maintenance treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in adult patients (≥16 years) experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).* *Tacrolimus ointment should be by doctors with a specialist interest and experience in treating atopic dermatitis using immunomodulatory therapy.*	Restricted use: tacrolimus 0.1% ointment (Protopic®) is accepted for restricted use within NHS Scotland. Licensed indication under review: the maintenance treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in adult patients (≥16 years) experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected). SMC Restriction: Use is restricted to initiation by doctors with a specialist interest and experience in treating atopic dermatitis using immunomodulatory therapy (this can include General Practitioners). Twice weekly maintenance therapy with tacrolimus ointment resulted in reduced disease exacerbations when compared to intermittent use only to treat disease exacerbations.	**Included** on the LJF for the indication in question. The SCP will be amended to include maintenance treatment. FC April 2013
13.12.10 *SMC Report No. 657/10* PRODUCT UPDATE (abbreviated submission)	tacrolimus granules for oral suspension (Modigraf®) *Astellas Pharma Ltd* • Prophylaxis of transplant rejection in adult and paediatric, kidney, liver or heart allograft recipients. • Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult and paediatric patients.	Restricted use: tacrolimus granules for Oral Suspension (Modigraf®) are accepted for restricted use within NHS Scotland. Indication under review: • Prophylaxis of transplant rejection in adult and paediatric, kidney, liver or heart allograft recipients. • Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult and paediatric patients. SMC restriction: for use in patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy and where small changes (less than 0.5mg) in dosing increments are required (e.g. in paediatric patients) or seriously ill patients who are unable to swallow tacrolimus capsules. Modigraf® granules for oral suspension offer 18% greater bioavailability than immediate release capsules and may have different bioavailability compared to other unlicensed tacrolimus suspensions in use in the past. Careful monitoring and possible dosage changes are needed when introducing treatment with Modigraf®. Tacrolimus granules for oral suspension are significantly more expensive than the capsule formulation.	Added to the Additional List, for use on the advice of a transplant specialist. FC March 2011
09.05.03 *SMC Report No.* 40/03	tadalafil (Cialis®) *Lilly ICOS* *Treatment of erectile dysfunction.*	Accepted for use: tadalafil may be prescribed under the conditions of Schedule 11 and represents an alternative to other phosphodiesterase type 5 (PSE-5) inhibitors, primarily for patients for whom the longer duration of action represents a significant advantage. This drug is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) Regulations 1995.	Approved for use - added to the Formulary as second choice. FC July 2003

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
08.06.09 *SMC Report No. 554/09* PRODUCT UPDATE (abbreviated submission)	tadalafil 2.5mg and 5mg film-coated tablets (Cialis®) *Lilly UK* *Regular once-daily administration in patients with erectile dysfunction responding to an on-demand regimen of tadalafil who anticipate frequent use (at least twice weekly).*	Accepted for use: tadalafil 2.5mg and 5mg tablets (Cialis®) are accepted for use in NHS Scotland for regular once-daily administration in patients with erectile dysfunction responding to an on-demand regimen of tadalafil who anticipate frequent use (at least twice weekly). Compared with this level of on-demand use, the low dose regular regimen is expected to be cost-neutral overall. Tadalafil represents an alternative to other phosphodiesterase type 5 inhibitors, primarily for patients for whom the longer duration of action represents a significant advantage. This drug is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) Regulations.	Added to the formulary as a prescribing note. FC July 2009
09.07.12 *SMC Report No: 710/11* Patient Access Scheme	tadalafil 20 mg tablets (Adcirca®) *Eli Lilly and Company Limited* *Treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II and III, to improve exercise capacity.*	Restricted use: tadalafil (Adcirca®) is accepted for restricted use within NHS Scotland for the treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II and III, to improve exercise capacity. SMC restriction: To initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists. Tadalafil demonstrated statistically significant improvement in 6 minute walking distance (6MWD) compared with placebo in patients with PAH, WHO-FC II or III. Approximately half of the study patients were receiving a concomitant endothelin receptor antagonist. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tadalafil. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	**Included** on the Additional List on the advice of a specialist in the Scottish Pulmonary Vascular Unit. FC August 2012
14.01.13 *SMC Report No. 849/12* NON SUBMISSION	tadalafil (Cialis®) 5mg film coated tablets Eli Lilly and Company Limited *Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.*	NOT RECOMMENDED: tadalafil (Cialis®) is not recommended for use within NHS Scotland for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
13.05.13 *SMC Report No: 877/13* NON SUBMISSION	tafamidis meglumine (Vyndaqel®) 20mg soft capsules *Pfizer Limited* *Treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment.*	NOT RECOMMENDED: tafamidis meglumine (Vyndaqel®) is not recommended for use within NHS Scotland for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment, The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.12.09 *SMC Report No: 581/09*	tafluprost 15 micrograms/ml preservative-free eye drops single-dose container (Saflutan®) *Merck Sharpe & Dohme Ltd* *Reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension - as monotherapy in patients: who would benefit from preservative-free eye-drops; who are insufficiently responsive to first-line therapy; or who are intolerant or contraindicated to first line therapy – or as adjunctive therapy to beta-blockers*.	Restricted Use: tafluprost preservative-free eye drops (Saflutan®) are accepted for restricted use within NHS Scotland for the reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension - as monotherapy: in patients who would benefit from preservative-free eye-drops, who are insufficiently responsive to first-line therapy, or who are intolerant or contraindicated to first-line therapy - or as adjunctive therapy to beta-blockers. Tafluprost is restricted to use in patients who cannot tolerate currently available prostaglandin preparations due to proven sensitivity to the preservative benzalkonium chloride. Preservative-free tafluprost has shown equivalence to a formulation of tafluprost with preservative in lowering intraocular pressure. The adverse event profile was similar for both formulations. The formulation of tafluprost with preservative has shown non-inferiority to a beta-blocker but failed to demonstrate non-inferiority to a prostaglandin comparator in a pre-specified primary analysis. Saflutan is the only preservative-free prostaglandin eye drop available.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2011
05.08.05 *SMC Report No. 149/04* PRODUCT UPDATE (abbreviated submission)	tamsulosin (Flomaxtra XL®) *Yamanouchi Pharma Ltd* *Prostatic hypertrophy.*	Accepted for use: tamsulosin hydrochloride film-coated extended release tablets 400micrograms (equivalent to 367micrograms tamsulosin) are accepted for use in NHS Scotland for functional symptoms of benign prostatic hypertrophy as an alternative to modified release capsules.	Added to the Formulary - new formulation of existing drug. Plain formulation to be retained in the Formulary as patent expires in 2006. FC October 2005
13.06.11 *SMC Report No. 654/10* *RESUBMISSION*	tapentadol, 50, 100, 150, 200 and 250mg prolonged-release tablets (Palexia® SR) *Grünenthal Ltd* *For the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.*	Restricted use: tapentadol prolonged-release (Palexia® SR) is accepted for restricted use within NHS Scotland for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. SMC restriction: patients in whom morphine sulphate modified release has failed to provide adequate pain control or is not tolerated. Results of a meta-analysis of three, 12-week studies suggest that tapentadol prolonged release has improved gastrointestinal tolerability and similar efficacy compared to another long-acting opioid included as an active control. The manufacturer's submission related only to the use of tapentadol prolonged release in severe chronic pain. SMC has not yet received a submission for tapentadol immediate release tablets for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics. Tapentadol immediate release tablets are not recommended for use in NHS Scotland.	Added to Formulary as Second choice drug after morphine for severe chronic pain. Note that the immediate release tapentadol tablets are not approved for use. FC January 2012
13.02.12 *SMC Report No. 773/12* *NON SUBMISSION*	tapentadol (Palexia®) 50 mg film-coated tablets *Grunenthal Ltd* *Relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.*	NOT RECOMMENDED: tapentadol (Palexia®) is not recommended for use within NHS Scotland as a relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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10.09.12 *SMC Report No 802/12*	tegafur/gimeracil/oteracil 15mg/4.35mg/ 11.8mg and 20mg/5.8mg/15.8mg hard capsules (Teysuno®) *Nordic Pharma Ltd.* *In adults for the treatment of advanced gastric cancer when given in combination with cisplatin.*	Restricted use: tegafur/gimeracil/oteracil (Teysuno®) is accepted for restricted use within NHS Scotland and is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin. SMC restriction: tegafur/gimeracil/oteracil is restricted to use in patients with advanced gastric cancer who are unsuitable for an anthracycline, fluorouracil and platinum triplet first-line regimen. In a multicentre, randomised, open-label clinical study in adult patients with advanced gastric cancer, tegafur/gimeracil/oteracil in combination with cisplatin was non-inferior to an intravenous fluoropyrimidine plus cisplatin with respect to overall survival.	**Not included** on the LJF because clinicians do not support the formulary inclusion. FC October 2012
12.12.11 *SMC Report No 742/11*	telaprevir, 375mg, film-coated tablets (Incivo®) *Janssen* *In combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.*	Accepted for use: telaprevir (Incivo®) is accepted for use within NHS Scotland in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders. In the pivotal phase III randomised study, the addition of telaprevir to current standard therapy in patients with genotype 1 chronic hepatitis C virus, who had failed previous therapy, significantly increased the proportion of patients who achieved a sustained virologic response.	Added to the Additional List, for Specialist use only. FC March 2012
12.12.11 *SMC Report No 743/11*	telaprevir 375mg film-coated tablets (Incivo®) *Janssen* *In combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve.*	Accepted for use: telaprevir (Incivo®) is accepted for use within NHS Scotland in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve. In the pivotal phase III randomised study, addition of telaprevir to current standard therapy in treatment-naïve patients with genotype 1 chronic hepatitis C virus, significantly increased the proportion of patients who achieved a sustained virologic response, even in patients treated for a shorter overall duration using response-guided therapy.	Added to the Additional List, for Specialist use only. FC March 2012
09.05.03 *SMC Report No. 39/03*	telmisartan/hydrochlorothiazide (MicardisPlus®) *Boehringer Ingelheim* *Hypertension.*	Restricted use: telmisartan / hydrochlorothiazide (MicardisPlus®) has efficacy similar to the antihypertensive effects of the individual constituents added together in the treatment of essential hypertension. No increased costs are associated with this product compared with telmisartan (Micardis®) alone. Angiotensin II receptor antagonists are an alternative to ACE inhibitors where these are not tolerated.	'Not preferred' as effective alternatives available. FC May 2003
10.05.10 *SMC Report No: 617/10* NON SUBMISSION	telmisartan (Micardis®) *Boehringer Ingelheim Limited* *Cardiovascular prevention.*	NOT RECOMMENDED: telmisartan (Micardis®), is not recommended for use within NHSScotland for use in cardiovascular prevention (to reduce cardiovascular morbidity in patients with manifest atherothrombotic cardiovascular disease history of coronary heart disease, stroke, or peripheral arterial disease) or type 2 diabetes mellitus with documented target organ damage. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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11.02.08 *SMC Report No. 438/08*	telbivudine, 600mg film-coated tablets (Sebivo®) *Novartis Pharmaceuticals UK Limited* *Treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and/or fibrosis.*	Accepted for use: telbivudine (Sebivo®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and/or fibrosis. For a number of therapeutic endpoints telbivudine proved to be equivalent or superior to a comparator nucleoside reverse transcriptase inhibitor.	'Not Preferred' as suitable alternatives exist. FC December 2008
10.05.04 *SMC Report No. 96/04*	temoporfin (Foscan®) *Biolitec Pharma* *Head and neck squamous cell carcinoma.*	NOT RECOMMENDED: temoporfin (Foscan®) is not recommended for use within NHS Scotland for the palliative treatment of patients with advanced head and neck squamous cell carcinoma failing prior therapies and unsuitable for radiotherapy, surgery or systemic chemotherapy. It is the first photosensitising drug licensed in the UK for use in photodynamic therapy (PDT) for the treatment of these patients. Its effect in terms of tumour mass reduction and improvement in quality of life were small and were only observed in patients with lesions less than 10mm deep, which were fully illuminated with activating light. The quality of life benefits resulting from palliation, particularly in this subgroup, were marginal and the economic case for its use over other palliative treatments was not made.	NOT RECOMMENDED
11.12.06 *SMC Report No. 244/06* RESUBMISSION	temozolomide 5, 20, 100 and 250mg capsules (Temodal®) *Schering Plough UK Ltd* *Treatment of newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and subsequently as monotherapy treatment.*	Restricted use: temozolomide (Temodal®) is accepted for restricted use within NHS Scotland for the treatment of newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and subsequently as monotherapy treatment. In a three-year follow up of the pivotal phase lll study, a significant survival benefit was seen over placebo in patients with good performance status and favourable prognostic markers. Temozolamide is restricted to patients who have had a partial or complete macroscopic resection of their tumour and with World Health Organisation (WHO) performance status 0 or 1.	Added to the LJF as first choice adjuvant treatment in patients with grade IV GBM. For specialist use only, FC April 2007
12.04.10 *SMC Report No. 617/10* NON SUBMISSION	temsirolimus (Torisel®) *Wyeth Pharmaceuticals* *Treatment of adult patients with relapsed and/or refractory mantle cell lymphoma [MCL].*	NOT RECOMMENDED: temsirolimus (Torisel®) is not recommended for use within NHS Scotland. Licensed indication under review: the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma [MCL]. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
14.06.02 *SMC Report No. 03/02*	tenofovir disoproxil fumarate (Viread®) *Gilead Sciences Ltd* *Combination antiretroviral therapy - HIV/AIDS.*	Accepted for use: tenofovir disoproxil fumarate is recommended in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. Tenofovir produces a clinically relevant viral response in heavily pre-treated patients experiencing early virological failure. Tenofovir should be initiated under the general supervision of specialists experienced in the management of HIV/AIDS patients.	Added to the Additional List as a further treatment option in HIV-infected patients - Specialist Use only. FC March 2004

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07.07.08 *SMC Report No. 479/08*	tenofovir disoproxil (as fumarate), 245 mg film-coated tablet (Viread®) *Gilead Sciences* *Treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.*	Accepted for use: tenofovir (Viread®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. Tenofovir has been shown to be significantly more effective than another nucleoside reverse transcriptase inhibitor in achieving a complete composite response (virological plus histological response) in a greater proportion of patients with chronic hepatitis B infection with HBeAg positive and HBeAg negative disease.	Added to Formulary as First choice, replacing entecavir and lamivudine for treatment of chronic hepatitis B. FC October 2008
12.09.11 *SMC Report No. 720/11*	tenofovir disoproxil (as fumarate), 245mg, film-coated tablet (Viread®) *Gilead Sciences Ltd* *The treatment of chronic hepatitis B in adults with decompensated liver disease.*	Accepted for use: tenofovir disoproxil (as fumarate) (Viread®) is accepted for use within NHS Scotland treatment of chronic hepatitis B in adults with decompensated liver disease. Interim results of an ongoing phase II study assessing the safety of tenofovir disoproxil in the treatment of chronic hepatitis B in patients with decompensated liver disease demonstrated that tenofovir was as well tolerated as another nucleoside/nucleotide analogue. Comparative efficacy was not tested in this study, but has been extrapolated from a mixed treatment comparison in treatment-naïve patients with compensated liver disease and hepatitis B e-antigen positive infection.	**Included** on the Additional List for the indication in question. FC December 2012
09.09.13 *SMC Report No: 900/13* PRODUCT UPDATE (abbreviated submission)	tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tablets (Viread®) *Gilead Sciences Ltd* *In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents.*	Restricted use: tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of HIV infection.	**Included** on the Additional List, Specialist Use only for the indication in question. FC August 2013

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
09.09.13 *SMC Report No: 904/13* PRODUCT UPDATE (abbreviated submission)	tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Viread®) *Gilead Sciences Ltd* *HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents.* *Hepatitis B infection - for the treatment of chronic hepatitis B in adolescents aged 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.*	Restricted use: tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland for: HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. Hepatitis B infection - for the treatment of chronic hepatitis B in adolescents aged 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. SMC has previously accepted tenofovir disoproxil for use in the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis and in patients with decompensated liver disease. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of hepatitis B infection and HIV infection.	**Included** on the Additional List, Specialist Use only for the indication in question. FC August 2013

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09.09.13 *SMC Report No: 905/13* PRODUCT UPDATE (abbreviated submission)	tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®) *Gilead Sciences Ltd* *HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate.* *Hepatitis B infection - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.*	Restricted use: tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland for: HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate. Hepatitis B infection - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. SMC has previously accepted tenofovir disoproxil for use in the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis and in patients with decompensated liver disease. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of hepatitis B infection and HIV infection.	***Paediatric patients*** - Included on the Additional List, Specialist Use only for the indication in question. ***Adult patients*** - Included on the Additional List for the indication in question when a solid dosage form is not appropriate. For Specialist Use only in the HIV indication. Shared Care Protocol will be revied for the hepatitis B infection. FC August 2013

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10.03.14 *SMC Report No. 940/14* Patient Access Scheme	teriflunomide, 14mg, film-coated tablets (Aubagio®) *Genzyme Ltd.* *Treatment of adults with relapsing remitting multiple sclerosis (MS).*	Restricted use: teriflunomide (Aubagio®) is accepted for restricted use within NHS Scotland for the treatment of adults with relapsing remitting multiple sclerosis (MS). SMC restriction: as an alternative to treatment with interferon beta or glatiramer acetate. Teriflunomide is not expected to be used for the treatment of patients with highly active disease. In two phase III, randomised, double-blind, placebo-controlled, parallel-group studies in adult patients with relapsing MS, teriflunomide significantly reduced the annualised relapse rate. In a phase III, randomised, single-blind, parallel-group study, teriflunomide showed similar efficacy to interferon beta. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of teriflunomide. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC May 2014
08.12.03 *SMC Report No. 71/03*	teriparatide (Forsteo®) *Eli Lilly* *Osteoporosis in post-menopausal women.*	Restricted use: teriparatide (Forsteo®) is accepted for restricted use within NHS Scotland for the treatment of established (severe) osteoporosis in post-menopausal women. This medicine should be restricted to initiation by specialists experienced in the treatment of osteoporosis following assessment of fracture risk including measurement of BMD. It is the first product to be licensed specifically for established (severe) post-menopausal osteoporosis. It has shown efficacy in reducing vertebral and non-vertebral fractures in post-menopausal women with prior vertebral fractures, particularly in a sub-group with documented severe osteoporosis. At the recommended daily dose it is expensive but appears to be cost-effective in women with proven osteoporosis who have developed fractures.	Added to the Formulary. For use when there has been an inadequate response to bisphosphonates. Use by designated Specialists only. FC May 2004
11.08.08 *SMC Report No. 490/08*	teriparatide, 750 micrograms/3ml solution for injection prefilled pen (Forsteo®) *Eli Lilly and Company Limited* *Treatment of osteoporosis in men at increased risk of fracture.*	NOT RECOMMENDED: teriparatide (Forsteo®) is not recommended for use within NHS Scotland for the treatment of osteoporosis in men at increased risk of fracture. Teriparatide was associated with a greater increase in lumbar spine bone mineral density than placebo. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
09.06.08 *SMC Report No. 487/08* NON SUBMISSION	teriparatide 20 micrograms/80 microlitres, solution for injection, in prefilled pen (Forsteo) *Eli Lilly and Company Limited* *Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.*	NOT RECOMMENDED: Teriparatide (Forsteo) is not recommended for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

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13.07.09 *SMC Report No: 555/09* PRODUCT UPDATE (abbreviated submission)	terlipressin acetate 0.12mg/ml solution for injection (Glypressin® Solution) *Ferring Pharmaceuticals Ltd* *Treatment of bleeding oesophageal varices.*	Accepted for use: terlipressin acetate 0.12mg/ml solution for injection (Glypressin® Solution) is accepted for use in NHS Scotland for the treatment of bleeding oesophageal varices in patients for whom terlipressin is an appropriate choice of therapy. It replaces a formulation that requires reconstitution and is associated with only a modest cost increase.	New formulation of a drug already included in the Formulary. FC December 2009
09.03.09 *SMC Report No. 308/06*	testosterone undecanoate, 1000mg/4ml oily solution for injection (Nebido®) *Bayer Schering Pharma* *Male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.*	Accepted for use: testosterone undecanoate (Nebido®) is accepted for use within NHS Scotland as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. Compared with alternative intramuscular preparations it offers the advantage of reduced frequency of dosing with less inter-dose fluctuation of testosterone levels.	Added to the Formulary. FC December 2009
08.12.03 *SMC Report No. 83/03*	testosterone gel (Testogel®) *Schering Healthcare Ltd* *Replacement therapy for adult male hypogonadism.*	Restricted use: testosterone (Testogel®), replacement therapy for adult male hypogonadism is accepted for restricted use within NHS Scotland. It offers an alternative to testosterone patches for those patients requiring a transdermal delivery system. Testosterone gel is at least as effective as testosterone patches and costs less, so is a cost effective transdermal treatment for this condition.	Added to the Formulary as a second choice treatment, replacing testosterone patches. FC August 2004
11.06.07 *SMC Report No. 372/07*	testosterone 2% gel (Tostran®) *ProStrakan* *Replacement therapy with testosterone for male hypogonadism when testosterone deficiency has been confirmed by clinical symptoms and laboratory analyses.*	Restricted use: testosterone 2% gel (Tostran®) is accepted for restricted use within NHS Scotland for replacement therapy with testosterone for male hypogonadism when testosterone deficiency has been confirmed by clinical symptoms and laboratory analyses. It is an alternative to other formulations of testosterone gel, with similar costs for equivalent doses. It is restricted to use as an alternative to testosterone patches for those patients requiring a transdermal delivery system. Testosterone gel is at least as effective as testosterone patches and costs less.	New formulation of a drug already included in the Formulary. FC April 2008
08.11.04 *SMC Report No. 128/04*	testosterone 30mg mucoadhesive buccal (prolonged release) tablets (Striant®) *Ardana Bioscience* *Testosterone replacement therapy.*	Restricted use: testosterone as mucoadhesive buccal tablet 30mg (Striant SR®) is accepted for restricted use within NHS Scotland as testosterone replacement therapy in men with primary or secondary hypogonadism. It offers an alternative to other routes, including transdermal application by patches or gel, for patients who would particularly benefit from this mode of administration where intramuscular treatment is not suitable.	Added to the Additional List. FC August 2005
10.07.06 *SMC Report No. 284/06* PRODUCT UPDATE (abbreviated submission)	testosterone 50mg/5g gel (Testim®) *Ispen Ltd* *Replacement therapy for adult male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.*	Restricted use: testosterone gel (Testim®) is accepted for restricted use within NHS Scotland as replacement therapy for adult male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. It is an alternative to another formulation of testosterone gel, of the same strength and cost, and is restricted to use as an alternative to testosterone gel patches for those patients requiring a transdermal delivery system. Testosterone is at least as effective as testosterone patches and costs less.	New formulation of a drug already included in the Formulary. FC October 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
10.09.07 *SMC Report No. 398/07*	testosterone 300micrograms/24 hours transdermal patch (Intrinsa®) *Procter and Gamble Pharmaceuticals UK Ltd* *Treatment of hypoactive sexual desire disorder (HSDD) in bilaterally oophorectomised and hysterectomised (surgically induced menopause) women receiving concomitant oestrogen therapy.*	NOT RECOMMENDED: testosterone transdermal patch (Intrinsa®) is not recommended for use within NHS Scotland for the treatment of hypoactive sexual desire disorder (HSDD) in bilaterally oophorectomised and hysterectomised (surgically induced menopause) women receiving concomitant oestrogen therapy. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.01.09 *SMC Report No. 525/08*	thalidomide, 50mg hard capsule (Thalidomide Pharmion®) *Celgene Ltd* *In combination with melphalan and prednisone, as first line treatment of patients with untreated multiple myeloma, aged 65 years or over or ineligible for high dose chemotherapy.*	Accepted for use: thalidomide (Thalidomide Pharmion®) is accepted for use within NHS Scotland in combination with melphalan and prednisone, as first line treatment of patients with untreated multiple myeloma, aged 65 years or over or ineligible for high dose chemotherapy. Thalidomide is prescribed and dispensed according to the Thalidomide Pharmion Pregnancy Prevention Programme. In the pivotal trial in patients aged 65 to 75 years, at 51.5 months median follow-up, the addition of thalidomide to melphalan and prednisone gave an overall survival advantage of 18.4 months.	Added to the Additional List, for Specialist Use only. FC July 2009
09.07.12 *SMC Report No. 790/12*	thiotepa 15mg and 100mg powder for concentrate for solution for infusion (Tepadina®) *Adienne S.r.l.* *In combination with other chemotherapy medicinal products:* *1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients;* *2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.*	NOT RECOMMENDED: thiotepa (Tepadina®) is not recommended for use within NHS Scotland in combination with other chemotherapy medicinal products: 1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients; 2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients. Two uncontrolled, non-randomised studies including patients with advanced non-Hodgkin's lymphoma or Hodgkin's disease have reported data for non-relapse mortality and overall survival. The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	NOT RECOMMENDED
10.07.06 *SMC Report No. 276/06*	tigecycline 50mg vial of powder tigecycline for intravenous infusion (Tygacil®) *Wyeth* *Treatment of complicated skin and soft-tissue infections.*	Restricted use: tigecycline (Tygacil®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft-tissue infections. Tigecycline is associated with clinical cure rates in patients with complicated skin and skin structure infections non-inferior to those with a combination of a glycopeptide and a monocyclic beta-lactam antibiotic. It is restricted to use as a 2nd or 3rd line agent under the advice of local microbiologists or specialists in infectious diseases.	Added to the Additional List, for Specialist Use only. FC September 2007
10.07.06 *SMC Report No. 277/06*	tigecycline 50mg vial of powder tigecycline for intravenous infusion (Tygacil®) *Wyeth* *Treatment of complicated intra-abdominal infection.*	Restricted use: tigecycline (Tygacil®) is accepted for restricted use within NHS Scotland for the treatment of complicated intra-abdominal infection. Tigecycline is associated with clinical cure rates in patients with complicated intra-abdominal infections non-inferior to those with a broad-spectrum beta-lactam antibiotic. It is restricted to 2nd line use under the advice of local microbiologists or specialists in infectious disease.	Added to the Additional List, for Specialist Use only. FC September 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
09.05.11 *SMC Report No. 699/11*	ticagrelor 90mg film-coated tablets (Brilique®) *AstraZeneca* *Co-administered with aspirin, for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (unstable angina, non ST elevation myocardial infarction [NSTEMI] or ST elevation myocardial infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).*	Accepted for use: ticagrelor film-coated tablets (Brilique®) are accepted for use within NHS Scotland. Indication under review: co-administered with aspirin, for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (unstable angina, non ST elevation myocardial infarction [NSTEMI] or ST elevation myocardial infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). As dual therapy with aspirin, ticagrelor demonstrated a significant reduction in ischaemic events compared with another antiplatelet drug without significantly increasing the incidence of study-defined major bleeding. Alternative treatments are available at a lower drug acquisition cost	**Included** on the LJF as a prescribing note for NSTEMI patients with a GRACE score equal to or greater than 140, aged less than 75 years; for twelve months in place of clopidogrel in this patient group. If the patient selection criteria were to change to wider group of patients then the use of ticagrelor will need to be reconsidered by the FC. FC August 2012
10.02.14 *SMC Report No. 941/14* PRODUCT UPDATE (abbreviated submission)	timolol, 1mg/g eye gel for single-dose container (Tiopex®) *Spectrum Thea Pharmaceuticals Limited* *Reduction of the elevated intraocular pressure in patients with:* *- ocular hypertension,* *- chronic open angle glaucoma.*	Restricted use: timolol gel eye drops (Tiopex®) are accepted for restricted use within NHS Scotland for reduction of the elevated intraocular pressure in patients with: - ocular hypertension, - chronic open angle glaucoma. SMC restriction: to use in patients who have proven sensitivity to preservatives. The cost of this once daily preservative-free formulation is significantly cheaper than the twice daily preservative-free preparation and may for some patients offer advantages in the lower concentration and reduced applications. Preserved timolol eye drops are included in the drug tariff and are significantly cheaper than preservative-free preparations.	**Included** on the LJF as a prescribing note, for the indication in question. FC February 2014
08.04.13 *SMC Report No. 868/13* NON SUBMISSION	timothy grass pollen allergen (GRAZAX®) 75,000 SQ-T oral lyophilisate *ALK-Abello Ltd* *Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.*	NOT RECOMMENDED: timothy grass pollen allergen (GRAZAX®) is not recommended for use within NHS Scotland in Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this extension to the indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.12.07 *SMC Report No. 411/07* PRODUCT UPDATE (abbreviated submission)	tiotropium 2.5micrograms respimat inhaler (Spiriva-Respimat®) *Boehringer Ingelheim Ltd* *Maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease.*	Restricted use: tiotropium respimat inhaler (Spiriva Respimat®) is accepted for restricted use within NHS Scotland as maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease. It may be used for patients in whom tiotropium is an appropriate choice of maintenance bronchodilator treatment but it is restricted to patients who have poor manual dexterity and therefore have difficulty using the Handihaler device.	Added to the LJF as a 'new formulation of a drug already in the formulary'. FC December 2007

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
06.12.02 *SMC Report No.19/02*	tiotropium bromide (Spiriva®) *Boehringer Ingelheim* *Maintenance treatment of chronic obstructive pulmonary disease.*	Accepted for use: Recommended for general use within NHS Scotland for maintenance treatment of chronic obstructive pulmonary disease (COPD). In clinical trials, tiotropium demonstrated superior efficacy to ipratropium and salmeterol in improving lung function (FEV_1). Generally, it has greater efficacy than ipratropium, and similar efficacy to salmeterol in improving dyspnoea, the use of rescue medication, the frequency of COPD exacerbations and hospitalisation due to exacerbations.	Approved for use - added to the LJF as a first choice drug for the treatment of moderate - severe COPD symptoms. FC July 2003
11.09.06 *SMC Report No. 226/05* RESUBMISSION	tipranavir, 250mg capsule (Aptivus®) *Boehringer Ingelheim Limited* *Treatment of HIV-1 infection in highly pre-treated adult patients with virus resistant to multiple protease inhibitors.*	Restricted use: tipranavir (Aptivus®) in combination with low dose ritonavir is accepted for restricted use within NHS Scotland for the treatment of HIV-1 infection in highly pre-treated adult patients with virus resistant to multiple protease inhibitors. At 48 weeks, tipranavir, in combination with low dose ritonavir, showed a significant improvement in the reduction of viral load compared with other protease inhibitor plus ritonavir regimens. Although the overall rate and type of adverse events were similar, tipranavir had a higher incidence of hepatotoxicity, hyperlipidaemia, bleeding events and rash. Tipranavir is more expensive than other protease inhibitors and it is restricted to patients with a tipranavir mutation score of less than 4.	Added to the Additional List, for Specialist Use only. For restricted use in HIV-1 infection in patients with multiple resistance to other protease inhibitors and a tipranavir mutation score of less than 4. FC December 2006
08.02.10 *SMC Report No. 602/10* PRODUCT UPDATE (abbreviated submission)	tipranavir (Aptivus®) 100mg/ml oral solution *Boehringer Ingelheim International* *Combination with low dose ritonavir is accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated children from 2 to 12 years of age with virus resistant to multiple protease inhibitors.*	Restricted use: tipranavir (Aptivus®) in combination with low dose ritonavir is accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated children from 2 to 12 years of age with virus resistant to multiple protease inhibitors. The marketing authorisation for tipranavir states that it should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. In adult patients the Scottish Medicines Consortium has restricted tipranavir to patients with a tipranavir mutation score of less than 4 and this restriction should also apply to this licence extension covering children from 2 to 12 years of age. Tipranavir is listed in the British National Formulary for Children for the treatment of HIV infection.	Added to the Additional List FC March 2010
08.02.10 *SMC Report No. 616/10* PRODUCT UPDATE (abbreviated submission)	tipranavir (Aptivus®) 250mg soft capsule *Boehringer Ingelheim International* *Combination with low dose ritonavir are accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors.*	Restricted use: tipranavir 250mg soft capsules (Aptivus®) in combination with low dose ritonavir are accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors. The marketing authorisation for tipranavir states that it should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. In adult patients the Scottish Medicines Consortium has restricted tipranavir to patients with a tipranavir mutation score of less than 4 and this restriction should also apply to this licence extension covering adolescents 12 years of age and older. Tipranavir is listed in the British National Formulary for Children for the treatment of HIV infection.	Added to the Additional List. FC March 2010
09.03.09 *SMC Report No. 314/06* NEW PRODUCT (abbreviated submission)	tobramycin 300mg/4ml nebuliser solution (Bramitob®) *Trinity Chiesi Pharmaceuticals Ltd* *Management of chronic pulmonary infection due to Pseudomonas aeruginosa in patients with cystic fibrosis aged 6 years and older.*	Accepted for use: tobramycin 300mg/4ml nebuliser solution (Bramitob®) is accepted for use in NHS Scotland for the management of chronic pulmonary infection due to Pseudomonas aeruginosa in patients with cystic fibrosis aged 6 years and older. Consideration should be given to official guidance on the appropriate use of antibacterial agents. This preparation offers an alternative to an existing nebuliser solution at a lower cost per dose.	Added to the Additional List, as an alternate brand of nebulised tobramycin. FC August 2011

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
11.06.12 *SMC Report No. 783/12* Patient Access Scheme	tobramycin 28mg inhalation powder, hard capsules (TOBI Podhaler®) *Novartis Pharmaceuticals UK Limited* *Suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis.*	Accepted for use: tobramycin inhalation powder, hard capsules (TOBI Podhaler®) is accepted for use within NHS Scotland as suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Tobramycin inhalation powder (TOBI Podhaler®) has demonstrated non-inferiority to tobramycin inhalation solution (via a nebuliser) measured by relative change in FEV_1 % predicted over three treatment cycles in a phase III, open-label, randomised study. This preparation offers an alternative to nebulised tobramycin. The company did not make a case for cost-effectiveness relative to other nebulised antimicrobials. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tobramycin inhalation powder (TOBI Podhaler®). This SMC advice is contingent upon the continuing availability of the patient access scheme in Scotland.	**Included** on the Additional List for the indication in question as an alternative option for patients instead of nebuliser. FC August 2012
18.01.10 *SMC Report No. 593/09*	tocilizumab, 20mg/ml concentrate for solution for injection (RoActemra®) *Roche* *For the treatment of moderate to severe active rheumatoid arthritis in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs or tumour necrosis factor antagonists.*	Restricted use: tocilizumab, (RoActemra®) is accepted for restricted use within NHS Scotland. Licensed indication under review: in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs or tumour necrosis factor antagonists. In these patients, toculizumab can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate. Addition of tocilizumab to disease-modifying anti-rheumatic drugs resulted in an increased response rate for reduction of disease activity. Restriction: It is restricted for use in combination therapy within NHS Scotland. The manufacturer did not present an economic case for monotherapy. Toculizumab should be used in accordance with the British Society of Rheumatology guidelines for prescribing TNF-α blockers in adults.	Added to the Additional List, for Specialist Use Only. FC May 2010
13.02.12 *SMC Report No. 754/12* Patient Access Scheme	tocilizumab, 20mg/mL concentrate for solution for infusion (RoActemra®) *Roche Products Limited* *For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate.*	Accepted for use: tocilizumab (RoActemra®) is accepted for use within NHS Scotland for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate. Tocilizumab was superior to placebo in reducing disease activity and fever in patients with persistent active systemic juvenile idiopathic arthritis despite treatment with NSAIDs and corticosteroids. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC January 2014

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10.09.12 *SMC Report No. 774/12* RESUBMISSION Patient Access Scheme	tocilizumab, 20mg/mL, concentrate for solution for infusion (RoActemra®) *Roche Products Limited* *Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.*	Restricted use: tocilizumab (RoActemra®) is accepted for restricted use within NHS Scotland. Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. SMC restriction: tocilizumab is restricted for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005). In a randomised, double-blind, controlled study conducted in patients who were intolerant to methotrexate, or for whom methotrexate was inappropriate, tocilizumab monotherapy was superior to a TNF antagonist for several clinically relevant outcomes (DAS28 scores, DAS28 remission, ACR response rates). This SMC advice takes account of the benefits of a Patient Access Scheme that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the availability of the Patient Access Scheme in NHS Scotland.	**Included** on the Additional List, Specialist Use only for the indication in question pending local protocol. FC October 2012
13.01.14 *SMC Report No. 930/13* PRODUCT UPDATE (abbreviated submission) Patient Access Scheme	tocilizumab, 20mg/mL concentrate for infusion (RoActemra®) *Roche Products Ltd* *Tocilizumab in combination with methotrexate is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with methotrexate.*	Accepted for use: tocilizumab (RoActemra®) is accepted for use within NHS Scotland in combination with methotrexate is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with methotrexate. Tocilizumab can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate. Tocilizumab has previously been accepted by SMC for treatment of adult rheumatoid arthritis and in active systemic juvenile idiopathic arthritis in patients from 2 years of age who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC January 2014
08.10.12 *SMC Report No. 696/11* RESUBMISSION	tocofersolan, 50mg/mL (corresponding to 74.5 IU tocopherol) oral solution (Vedrop®) *Orphan Europe UK* *Vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region.*	NOT RECOMMENDED: tocofersolan oral solution (Vedrop®) is not recommended for use within NHS Scotland for vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region. In an open-label, single-arm study, 96% of patients had an improved or stable neurological score after 2.5 years of treatment with tocofersolan. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED

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18.01.10 *SMC Report No. 605/10* NON SUBMISSION	tolvaptan 15mg tablet (Samsca®) *Otsuka UK* *Treatment of adult patients with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH).*	NOT RECOMMENDED: tolvaptan (Samsca®) is not recommended for use within NHSScotland for the treatment of adult patients with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.01.04 *SMC Report No. 75/03*	topiramate (Topamax®) *Janssen Cilag* *Epilepsy.*	Restricted use: topiramate (Topamax®) is accepted for restricted use within NHS Scotland for its extended (monotherapy) indication. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. Topiramate should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contraindications, interactions or poor tolerance. Its use for second-line therapy in epilepsy is unaffected by this recommendation.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
11.09.06 *SMC Report No. 297/06*	topiramate 25, 50mg tablets, 25, 50mg sprinkle capsules (Topamax®) *Janssen-Cilag Limited* *Prophylaxis of migraine headache in adults.*	Restricted use: topiramate (Topamax®) is accepted for restricted use within NHS Scotland for the prophylaxis of migraine headache in adults. It should be restricted to initiation by specialists and treatment should be managed under specialist supervision or shared care arrangements in patients who have not responded to prophylactic treatment with at least one other agent.	Added to Formulary as prescribing note – to be initiated following specialist advice. FC June 2008
07.05.07 *SMC Report No. 366/07*	topotecan 1mg, 4mg powder for concentrate for solution for infusion (Hycamtin®) *GlaxoSmithKline* *Treatment of patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.*	NOT RECOMMENDED: topotecan (Hycamtin®) is not recommended for use within NHS Scotland for the treatment of patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate. In a trial comparing oral topotecan plus active symptom control (ASC) to ASC alone the difference in median survival was 12 weeks, in favour of the oral topotecan plus ASC group. Topotecan is not available as an oral formulation in the UK, however, in one trial the response rate and median survival duration were similar for oral and IV topotecan groups. The treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED
10.12.07 *SMC Report No. 421/07*	topotecan 1mg, 4mg powder for concentrate for solution for infusion (Hycamtin®) *GlaxoSmithKline* *In combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with stage IVB disease.*	Restricted use: topotecan (Hycamtin®) is accepted for restricted use within NHS Scotland in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with stage IVB disease. It is restricted to patients who are cisplatin-naïve. In an open-label study, overall and progression-free survival were significantly longer for cisplatin plus topotecan compared with cisplatin alone. Haematological adverse events were more common in the cisplatin plus topotecan group. The economic submission demonstrated that topotecan plus cisplatin was cost effective compared to cisplatin alone in cisplatin-naïve patients. However, the manufacturer's justification of the treatment's cost in relation to its health benefit was not sufficient to gain acceptance by SMC for use in patients with previous exposure to cisplatin.	Added to the Formulary as recommended by SMC Advice. Not Preferred for use in patients, who have received cisplatin previously (see table on non-SMC drugs). FC November 2008

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
14.04.09 *SMC Report No. 545/09*	topotecan 0.25mg, 1mg hard capsules (Hycamtin®) *GlaxoSmithKline* *As monotherapy for the treatment of adult patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.*	Restricted use: topotecan capsules (Hycamtin®) are accepted for restricted use within NHS Scotland as monotherapy for the treatment of adult patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate. The efficacy of topotecan capsules relative to standard IV chemotherapy is unknown. Topotecan capsules are restricted to use in patients for whom standard intravenous chemotherapy is inappropriate and who would otherwise receive best supportive care. In one study, oral topotecan plus best supportive care (BSC) was superior to BSC alone for the primary endpoint of median survival.	Added to the Additional List, for Specialist Use only. FC July 2009
11.07.11 *SMC Report No. 452/08* 2nd RESUBMISSION	trabectedin (Yondelis®) *Pharma Mar SA* *Treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.*	NOT RECOMMENDED trabectedin (Yondelis®) is not recommended for use within NHS Scotland. Indication under review: treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. In a phase II randomised study in patients with advanced leiomyosarcoma and liposarcoma in which two trabectedin dose schedules were compared, the licensed 3-weekly schedule was superior to the alternative schedule for the primary endpoint, time to progression. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED
13.09.10 *SMC Report No. 634/10*	trabectedin (Yondelis®) *Pharma Mar SA Ltd* *Trabectedin in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.*	NOT RECOMMENDED: trabectedin (Yondelis®) is not recommended for use within NHS Scotland. Indication under review: Trabectedin in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer. In an open-label randomised controlled study trabectedin in combination with PLD was significantly superior to PLD monotherapy in terms of progression free survival. There was a significant difference in an exploratory interim analysis of overall survival in the sub-group of patients with partially platinum-sensitive disease. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and in addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC	NOT RECOMMENDED
13.02.06 *SMC Report No. 236/06*	tramadol 37.5mg/paracetamol 325mg tablet (Tramacet®) *Janssen-Cilag* *Symptomatic treatment of moderate to severe pain.*	NOT RECOMMENDED: tramadol 37.5mg/paracetamol 325mg tablet (Tramacet®) is not recommended for use within NHS Scotland for the symptomatic treatment of moderate to severe pain. Tramacet had similar efficacy to another combination analgesic in clinical studies, though the dose of paracetamol in the other analgesic preparation was lower than that usually used in the UK. Tramacet costs significantly more than its individual components prescribed separately.	NOT RECOMMENDED
09.07.07 *SMC Report No. 386/07* NON SUBMISSION	trastuzumab (Herceptin®) *Roche Pharmaceuticals* *In combination with an aromatase inhibitor for metastatic breast cancer.*	NOT RECOMMENDED: trastuzumab (Herceptin®) in combination with an aromatase inhibitor is not recommended for metastatic breast cancer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
09.06.06 *SMC Report No. 278/06*	trastuzumab 150mg vial (Herceptin®) *Roche* *Treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable).*	Restricted use: trastuzumab (Herceptin®) is accepted for restricted use within NHSScotland for the treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). In the pivotal trial, the addition of one year of 3-weekly trastuzumab after adjuvant chemotherapy significantly increased disease-free survival compared with that in the observation group. The trial excluded patients with a range of cardiovascular conditions and trastuzumab treatment for early breast cancer is not recommended in such patients. In patients treated with trastuzumab for early breast cancer, monitoring of cardiac function is required before treatment, every three months during treatment and for up to two years after treatment has stopped. Trastuzumab in this indication is restricted to use by breast cancer specialists.	Added to LJF as first choice for use in patients with HER2 positive early breast cancer following surgery, chemotherapy and radiotherapy (if applicable). For specialist use only. FC April 2007
07.02.11 *SMC Report No. 623/10* RESUBMISSION	trastuzumab, 150mg powder for concentrate for solution for infusion (Herceptin®) *Roche* *In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herceptin should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.*	NOT RECOMMENDED: trastuzumab (Herceptin®) is not recommended for use within NHS Scotland. Indication under review: in combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herceptin is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay. The addition of trastuzumab to doublet chemotherapy has shown benefits in overall and progression-free survival and tumour response. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and the economic case was not sufficiently robust to gain acceptance by SMC.	NOT RECOMMENDED
13.01.14 *SMC Report No. 928/13*	trastuzumab, 600mg/5mL solution for injection (Herceptin®) *Roche Products Ltd* *Treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (full details of licensed indication presented later in advice document).*	Restricted use: trastuzumab 600mg/5mL solution for injection (Herceptin®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (full details of licensed indication presented later in advice document). Trastuzumab should only be used in patients with metastatic or early breast cancer whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. SMC restriction: Subcutaneous trastuzumab injection is accepted for use in line with previous SMC advice for intravenous trastuzumab (this excludes its use in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab). In a phase III randomised, open-label clinical study in patients with HER2-positive early breast cancer, subcutaneous trastuzumab was non-inferior to intravenous trastuzumab for the co-primary pharmacokinetic and efficacy endpoints of serum trough concentration (C_{trough}) at pre-dose cycle 8 before surgery and pathological complete response.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC April 2014

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09.02.04 *SMC Report No. 60/04*	travoprost (Travatan®) *Alcon Laboratories* *Ocular hypertension/open angle glaucoma.*	Restricted use: travoprost (Travatan®) is accepted for restricted use within NHS Scotland for the treatment of raised intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma. Use of travoprost, as monotherapy, should be restricted to patients who have contraindications to beta-blockers or have a history of adverse reactions to this group of drugs. It may also be indicated in addition to beta-blockers when required. It is one of a number of topical ocular prostaglandin analogue preparations licensed in the UK for this indication. In reducing IOP it is comparable in effect to other drugs in its class.	Added to the Additional List. FC April 2004 First choice prostaglandin analogue in LJF FC July 2010
07.08.06 *SMC Report No. 294/06* PRODUCT UPDATE (abbreviated submission)	travoprost 0.004% / timolol 0.5% eye drops (Duotrav®) *Alcon Laboratories (UK) Ltd* *Intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues alone.*	Accepted for use: travoprost/timolol (Duotrav®) eye drops are accepted for use in NHS Scotland for whom this is an appropriate combination of agents. They decrease intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues alone. There is no significant additional cost associated with the combination product compared with the individual components and it allows patients to administer fewer drops.	Added to the LJF as a prescribing note FC July 2010
08.05.06 *SMC Report No. 269/06* NON SUBMISSION	triptorelin 3.75mg (Gonapeptyl Depot®) *Ferring Pharmaceuticals Ltd* *Advanced, hormone-dependent prostate carcinoma.*	NOT RECOMMENDED: Gonapeptyl Depot® is not recommended for use within NHSScotland for the treatment of advanced, hormone-dependent prostate carcinoma. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
08.05.06 *SMC Report No. 270/06* NON SUBMISSION	triptorelin 3.75mg (Gonapeptyl Depot®) *Ferring Pharmaceuticals Ltd* *Symptomatic endometriosis.*	NOT RECOMMENDED: Gonapeptyl Depot® is not recommended for use within NHSScotland for symptomatic endometriosis confirmed by laparoscopy when suppression of the ovarian hormonogenesis is indicated to the extent that surgical therapy is not primarily indicated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
09.05.05 *SMC Report No. 160/05*	triptorelin 3.75mg depot injection (Gonapeptyl Depot®) *Ferring Pharmaceuticals* *New indication: central precocious puberty.*	Accepted for use: triptorelin (Gonapeptyl Depot®) is accepted for use within NHS Scotland for the treatment of confirmed central precocious puberty in girls under nine years and boys under ten years.	Added to the LJF for Children as second choice drug. FC May 2005
10.10.05 *SMC Report No. 207/05* PRODUCT UPDATE (abbreviated submission)	triptorelin 11.25mg injection (Decapeptyl SR®) *Ipsen Ltd* *Endometriosis.*	Accepted for use: triptorelin 11.25mg injection every 3 months (Decapeptyl SR®) is accepted for use within NHS Scotland for the treatment of endometriosis in patients for whom the use of triptorelin is appropriate and who would benefit from reduced frequency of administration compared with triptorelin 3mg injection every 4 weeks (Decapeptyl®).	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC May 2007
11.12.06 *SMC Report No. 331/06* PRODUCT UPDATE (abbreviated submission)	triptorelin 11.25mg vial for injection (Decapeptyl SR®) *Ipsen Ltd* *Treatment of precocious puberty (onset before 8 years in girls and 9 years in boys).*	Accepted for use: triptorelin 11.25mg vial for injection (Decapeptyl SR®) is accepted for use in NHS Scotland for the treatment of precocious puberty (onset before 8 years in girls and 9 years in boys). For patients for whom this drug is appropriate, it is associated with an increased dose interval (3 months vs. 1 month) and reduced costs compared to an existing pre-filled syringe formulation of triptorelin.	New formulation of a drug already included in the Formulary. FC October 2007

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12.07.04 *SMC Report No. 109/04* PRODUCT UPDATE (abbreviated submission)	triptorelin acetate (Decapeptyl® SR 11.25mg) *Ipsen Ltd* *Advanced prostate cancer.*	Accepted for use: Decapeptyl® SR 11.25mg is accepted for use within NHS Scotland for the treatment of advanced prostate cancer in patients for whom the use of triptorelin is appropriate and who would benefit from reduced frequency of administration compared with Decapeptyl® SR 3mg (every 3 months vs every 28 days).	Added to the Formulary as first choice gonadorelin analogue for advanced prostate cancer instead of goserelin or leuprorelin. FC May 2005
13.06.11 *SMC Report No. 705/11* PRODUCT UPDATE (abbreviated submission)	triptorelin (Decapeptyl SR®) 22.5mg powder and solvent for suspension for injection *Ipsen Ltd* •*Treatment of patients with locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration.* •*Treatment of metastatic prostate cancer.*	Accepted for use: triptorelin pamoate 22.5mg (Decapeptyl SR®) is accepted for use within NHS Scotland. This new preparation of triptorelin allows 6-monthly administration (as triptorelin pamoate in a 22.5mg dose). Triptorelin 11.25mg (as acetate) is administered every 3 months and has previously been accepted by SMC. Bioequivalence of the pamoate and acetate salts has been demonstrated and the new preparation is cost neutral. Note: The indication for triptorelin 11.25mg formulation was reworded in 2007 to achieve consistency Europe-wide and now reads as per the indication for triptorelin 22.5mg.	Added to the Formulary, as a new formulation of a product already included. FC May 2011
11.06.12 *SMC Report No. 796/12* NON SUBMISSION	triptorelin pamoate (Salvacyl®) 11.25mg powder and solvent for suspension for injection *Ipsen Ltd* *Reversible reduction of testosterone to castrate levels in order to decrease sexual drive in adult men with severe sexual deviations.*	NOT RECOMMENDED: triptorelin pamoate (Salvacyl®) is not recommended for use within NHS Scotland as reversible reduction of testosterone to castrate levels in order to decrease sexual drive in adult men with severe sexual deviations. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
08.02.10 *SMC Report No. 600/10* PRODUCT UPDATE (abbreviated submission)	trospium chloride 20 mg film-coated tablets (Flotros®) *Galen Limited* *Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder (e.g. idiopathic or neurologic detrusor overactivity).*	Accepted for use: trospium chloride (Flotros®) is accepted for use in NHS Scotland for symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder (e.g. idiopathic or neurologic detrusor overactivity). In patients for whom an immediate-release formulation of trospium chloride is an appropriate treatment, this preparation offers an alternative to an existing preparation at a lower cost.	'Not preferred' in Lothian as suitable alternatives exist. FC March 2010
08.02.10 *SMC Report No. 599/10*	ulipristal acetate, 30mg tablet (EllaOne®) *HRA Pharma UK Ltd* *Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.*	Accepted for use: ulipristal acetate (EllaOne®) is accepted for use within NHS Scotland for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. When administered within the licensed time frame for ulipristal or an active comparator for emergency hormonal contraception, contraceptive efficacy with ulipristal was non-inferior to that with the comparator in individual studies and statistically superior in a meta-analysis of two studies. Other treatments are available at lower drug acquisition cost.	Added to the LJF as second choice for women presenting for emergency contraception. FC May 2010

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11.02.13 *SMC Report No. 834/13*	ulipristal acetate, 5mg, tablet (Esmya®) *PregLem Ltd.* *Pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months.*	Accepted for use: ulipristal acetate (Esmya®) is accepted for use within NHS Scotland for pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months. Ulipristal was superior to placebo and non-inferior to a gonadotrophin releasing hormone (GnRH) agonist for reducing uterine bleeding in pre-operative women with uterine fibroids and excessive bleeding.	**Included** on the LJF as a prescribing note, for the indication in question. A new formulary section will be created to accommodate this treatment. FC July 2013
12.08.13 *SMC Report No. 889/13* PRODUCT UPDATE (abbreviated submission)	ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) *Dr Falk Pharma UK Ltd* *For the dissolution of cholesterol gallstones in the gall bladder. For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis.*	Accepted for use: ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) is accepted for use within NHS Scotland for the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s). For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis. Ursodeoxycholic acid 500mg film-coated tablets have demonstrated bioequivalence to ursodeoxycholic acid capsules at the same dose. Relative costs may vary slightly depending on the pack size used.	**Included** on the Additional List for the indication in question. FC August 2013
08.02.10 *SMC Report No. 572/09* Patient Access Scheme	ustekinumab, 45mg solution for injection (Stelara®) *Janssen-Cilag Ltd* *For the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen and UVA treatment (PUVA).*	Restricted use: ustekinumab (Stelara®) is accepted for restricted use within NHS Scotland for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen and UVA treatment (PUVA). Significantly more patients treated with ustekinumab achieved at least 75% improvement in their Psoriasis Area and Severity Index (PASI) score at week 12, compared with those treated with a tumour necrosis factor alpha antagonist. Continued treatment should be restricted to patients who achieve a PASI 75 response within 16 weeks. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ustekinumab. This SMC advice is dependent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist Use only. FC May 2010
10.03.14 *SMC Report No. 944/14*	ustekinumab 45mg solution for injection in pre-filled syringe (Stelara®) *Janssen-Cilag Ltd* *Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate.*	Restricted use: ustekinumab (Stelara®) is accepted for restricted use within NHS Scotland, alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate. SMC restriction: for use in patients with active psoriatic arthritis who have failed on, or are unsuitable for, treatment with an anti-TNF drug. Significantly more patients with active psoriatic arthritis who were treated with ustekinumab achieved at least 20% response on American College of Rheumatology criteria (ACR 20) at 24 weeks compared with those treated with placebo.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC April 2014
06.12.02 *SMC Report No. 21/02*	valganciclovir (Valcyte®) *Roche* *Management of cytomegalovirus (CMV) retinitis in patients with AIDS.*	Restricted use: valganciclovir offers a convenient oral alternative to ganciclovir. It is currently only licensed for the management of CMV retinitis in AIDS patients. Its use should be under the overall supervision of an expert ophthalmologist and a physician experienced in the management of HIV / AIDS patients.	Added to the Additional List as a replacement for IV ganciclovir (for Specialist Use only). FC January 2004

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08.09.03 *SMC Report No. 62/03* PRODUCT UPDATE (abbreviated submission)	valganciclovir (Valcyte®) *Roche* *Prevention of cytomegalovirus (CMV) disease in CMV-negative patients who have received a solid organ transplanted from a CMV-positive donor.*	Restricted use: valganciclovir has been approved for prevention of cytomegalovirus (CMV) disease in CMV-negative patients who have received a solid organ transplanted from a CMV-positive donor. It can be given once daily compared with three times daily for existing treatment, thereby improving compliance and convenience. Use of valganciclovir should only be initiated by physicians in transplantation or infectious disease units.	Added to the Additional List as a replacement for ganciclovir. Shared care protocol to be developed. FC January 2004
07.12.09 *SMC Report No 586/09* PRODUCT UPDATE (abbreviated submission)	valganciclovir powder for 50mg/ml oral solution (Valcyte®) *Roche* *For the induction and maintenance treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).*	Restricted use: valganciclovir powder for 50mg/ml oral solution (Valcyte®) is accepted for restricted use in NHS Scotland for the induction and maintenance treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). Its use should be under the overall supervision of an expert ophthalmologist and a physician experienced in the management of HIV / AIDS patients. In patients for whom valganciclovir is an appropriate choice of therapy this is the only licensed formulation for those undergoing haemodialysis (creatinine clearance <10ml/minute). Otherwise its use should be restricted to patients unable to use the less costly solid oral dosage form.	New formulation of a drug already included in the Formulary. FC December 2009
07.12.09 *SMC Report No 587/09* PRODUCT UPDATE (abbreviated submission)	valganciclovir powder for 50mg/ml oral solution (Valcyte®) *Roche* *For the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.*	Restricted use: valganciclovir powder for 50mg/ml oral solution (Valcyt®) is accepted for restricted use in NHS Scotland for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor. Valganciclovir should only be initiated by physicians experienced in the care of post-transplant patients. In patients for whom valganciclovir is an appropriate choice of therapy this is the only licensed formulation for those undergoing haemodialysis (creatinine clearance <10ml/minute). Otherwise its use should be restricted to patients unable to use the less costly solid oral dosage form.	New formulation of a drug already in the Formulary. FC December 2009
17.01.11 *SMC Report No 662/10*	valganciclovir, 450mg tablets, 50mg/ml powder for oral solution (Valcyte®) *Roche Products Ltd* *Prevention of cytomegalovirus (CMV) disease in CMV negative patients who have received a solid organ transplant from a CMV positive donor. The marketing authorisation has been amended to allow the duration of CMV prophylaxis in kidney transplant patients to be increased from 100 days to 200 days post-transplantation.*	Restricted use: Valganciclovir (Valcyte®) is accepted for restricted use within NHS Scotland. Indication under review: prevention of cytomegalovirus (CMV) disease in CMV negative patients who have received a solid organ transplant from a CMV positive donor. The marketing authorisation has been amended to allow the duration of CMV prophylaxis in kidney transplant patients to be increased from 100 days to 200 days post-transplantation SMC restriction: valganciclovir should be initiated by physicians experienced in the care of post-transplant patients. In a randomised controlled study there was a significant reduction in the incidence of CMV disease at 12 months following 200-day versus 100-day prophylaxis.	Added to the Additional Lists. FC March 2012
09.05.05 *SMC Report No. 162/05*	valsartan 40mg, 80mg and 160mg capsules and tablets (Diovan®) *Novartis Pharmaceuticals* *New Indication: following myocardial infarction in patients with clinical or radiological signs of left ventricular failure and/or left ventricular systolic dysfunction.*	Restricted use: valsartan (Diovan®) is accepted for restricted use within NHS Scotland to improve survival following myocardial infarction (MI) in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction. Valsartan has been shown to be as effective as the ACE inhibitor, captopril, in this patient population and should be considered a second-line alternative in patients who cannot tolerate an ACE inhibitor. The economic evaluation demonstrates that valsartan is only cost effective in the patient population that is intolerant of ACE inhibitors.	Added to the Additional List to improve survival following MI in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction, who are intolerant of ACE inhibitors. FC August 2005

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11.02.08 *SMC Report No. 351/07* PRODUCT UPDATE (abbreviated submission)	valsartan 320mg tablet (Diovan®) *Novartis Pharmaceuticals UK Ltd* *Treatment of hypertension.*	Accepted for use: valsartan 320mg tablet (Diovan®) is accepted for use in NHS Scotland for the treatment of hypertension. In patients for whom the use of valsartan is appropriate it allows administration of a 320mg dose as a single tablet at less cost than 2 x 160mg capsules. Angiotensin receptor blockers are an alternative to ACE inhibitors where these are not tolerated.	'Not preferred' as suitable alternatives exist. Note - this is for treatment of hypertension. FC March 2008
13.09.04 *SMC Report No. 121/04*	valsartan/hydrochlorothiazide (Co-Diovan®) *Novartis Pharmaceuticals UK Ltd* *Treatment of essential hypertension in patients whose blood pressure is not adequately controlled on valsartan monotherapy.*	Accepted for use: valsartan/hydrochlorothiazide (Co-Diovan®) is accepted for use within NHS Scotland for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on valsartan monotherapy. No increased costs are associated with this product compared with valsartan (Diovan®) alone. Angiotensin receptor blockers are an alternative to ACE inhibitors where these are not tolerated. This fixed dose combination is one of many options for the treatment of hypertension, including other angiotensin receptor blocker/diuretic combinations, many of which are less expensive.	'Not preferred' as effective alternatives available. FC November 2004
17.01.11 *SMC Report No. 649/10* PRODUCT UPDATE (abbreviated submission)	valsartan (Diovan®) 40, 80, 160, 320mg tablets *Novartis Pharmaceuticals UK Ltd* *Treatment of hypertension in children and adolescents 6 to 18 years of age.*	Restricted use: Valsartan (Diovan®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of hypertension in children and adolescents 6 to 18 years of age. SMC restriction: use should be on the recommendation of a paediatric specialist consultant. The licence for the adult indication pre-dates SMC.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC March 2012
11.06.12 *SMC Report No. 797/12* NON SUBMISSION	vandetanib (Caprelsa®) 100 mg / 300mg film coated tablets *AstraZeneca UK Limited* *Treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease.*	NOT RECOMMENDED: vandetanib (Caprelsa®) is not recommended for use within NHS Scotland for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED
06.06.03 *SMC Report No. 47/03*	vardenafil (Levitra®) *GlaxoSmithKline / Bayer* *Treatment of erectile dysfunction.*	Accepted for use: vardenafil represents an acceptable alternative to other phosphodiesterase type 5 inhibitors for erectile dysfunction. This drug is likely to be subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of Schedule 11 of the National Health Service (General Medical Services) (Scotland) Regulations 1995.	'Not preferred' as effective alternatives available. FC July 2003

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10.10.11 *SMC Report No. 727/11*	vardenafil 10mg orodispersible tablet (Levitra®) *Bayer Healthcare* *Treatment of erectile dysfunction (ED) in adult men. ED is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Levitra to be effective, sexual stimulation is required.*	Restricted use: vardenafil orodispersible tablet (Levitra®) is accepted for restricted use within NHS Scotland. Treatment of erectile dysfunction (ED) in adult men. ED is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for vardenafil to be effective, sexual stimulation is required. SMC restriction: use is restricted to patients in whom an orodispersible tablet is an appropriate formulation. Vardenafil is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) regulations. Two placebo controlled, studies have shown that vardenafil orodispersible is significantly better than placebo in the treatment of erectile dysfunction in men. No comparative evidence against other medicines for erectile dysfunction was presented.	**Not included** on the LJF because clinicians do not support the formulary inclusion. 'Not Preferred' as suitable alternatives exist. FC May 2012
15.01.07 *SMC Report No. 336/06*	varenicline 1mg tablets (Champix®) *Pfizer Ltd* *Smoking cessation in adults.*	Accepted for use: varenicline tablets (Champix®) is accepted for use within NHS Scotland for smoking cessation in adults. It should be used only as a component of a smoking cessation support programme. The benefits of an additional treatment course in those who have stopped smoking after the initial 12 weeks of therapy appear modest. Efficacy and safety in patients with significant co-morbidity are uncertain.	Added to the LJF as a prescribing note. FC April 2007
08.10.12 *SMC Report No. 681/11* Patient Access Scheme	velaglucerase alfa 400 units powder for solution for infusion (VPRIV®) *Shire Pharmaceuticals Limited* *Long-term enzyme replacement therapy in patients with type 1 Gaucher disease.*	Accepted for use: velaglucerase alfa (Vpriv®) is accepted for use within NHS Scotland for Long-term enzyme replacement therapy in patients with type 1 Gaucher disease. Velaglucerase alfa has been shown to be non-inferior to another enzyme replacement treatment in patients with type 1 Gaucher disease. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of velaglucerase. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC November 2012
09.12.13 *SMC Report No. 792/12* RESUBMISSION Patient Access Scheme	vemurafenib 240mg film-coated tablet (Zelboraf®) *Roche Products Ltd.* *As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.*	Restricted use: vemurafenib (Zelboraf®) is accepted for restricted use within NHS Scotland as monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. SMC restriction: for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma. Vemurafenib significantly increases overall survival and progression-free survival compared with a current standard chemotherapy for patients with previously untreated unresectable stage IIIC or stage IV melanoma with V600 BRAF mutation. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of vemurafenib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC February 2014
11.08.08 *SMC Report No. 501/08* NON SUBMISSION	venlafaxine (Efexor® XL) *Wyeth Pharmaceuticals* *Treatment of moderate to severe generalised social anxiety disorder/social phobia in adults.*	NOT RECOMMENDED: venlafaxine extended release capsules (Efexor XL) are not recommended for use within NHSScotland for the treatment of moderate to severe generalised social anxiety disorder/social phobia in adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland	NOT RECOMMENDED

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation **For more details see www.scottishmedicines.org.uk**	Lothian Recommendation and Formulary Committee Comments **For more details see www.ljf.scot.nhs.uk**
07.04.08 *SMC Report No. 435/07*	vildagliptin 50mg tablets (Galvus®) *Novartis* *Treatment of type 2 diabetes mellitus.*	Restricted use: vildagliptin (Galvus®) is accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin. It is restricted to use in patients only when the addition of sulphonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of glycated haemoglobin (HbA1c), is similar to thiazolidinedione drugs added at this stage in therapy. It appears to have minimal effect on body weight. Vildagliptin is also licensed for use in combination with sulphonylureas or thiazolidinedione drugs for the treatment of type 2 diabetes. The manufacturer's submission related only to the use of vildagliptin in combination with metformin. SMC cannot recommend the use of vildagliptin in combination with these agents.	Added to Formulary as a prescribing note. FC June 2008 'Not preferred' as a suitable alternative exists. FC Novemeber 2010
12.10.09 *SMC Report No. 571/09*	vildagliptin 50mg tablets (Galvus®) *Novartis* *Treatment of type 2 diabetes mellitus.*	Accepted for use: vildagliptin (Galvus®) is accepted for use within NHS Scotland for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea or for whom metformin is inappropriate due to contraindications or intolerance. When added to a sulphonylurea, vildagliptin had a modest beneficial effect on glycated haemoglobin (HbA1C). Vildagliptin is also licensed for use in combination with metformin or thiazolidinedione drugs for the treatment of type 2 diabetes. SMC has already issued advice on use in combination with metformin. As this submission from the manufacturer related only to the use of vildagliptin in combination with a sulphonylurea, SMC cannot recommend the use of vildagliptin in combination with thiazolidinedione drugs.	'Not preferred' as a suitable alternative exists. FC Novemeber 2010.
07.07.08 *SMC Report No 477/08* ABBREVIATED SUBMISSION	vildagliptin 50mg / metformin hydrochloride 850mg film coated tablets and vildagliptin 50mg / metformin hydrochloride 1000mg film coated tablets (Eucreas® 50mg/850mg and 50mg/1000mg) *Novartis Pharmaceuticals UK Limited* *Treatment of type 2 diabetes mellitus patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets.*	Restricted use: vildagliptin 50mg/metformin hydrochloride 850mg film coated tablets and vildagliptin 50mg/metformin hydrochloride 1000mg film coated tablets (EucreasÒ 50mg/850mg and 50mg/1000mg) are accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. The addition of vildagliptin to metformin is restricted to use in patients only when the addition of sulphonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of glycated haemoglobin (HbA1c), is similar to thiazolidinedione drugs added at this stage in therapy. It appears to have minimal effect on body weight.	Added to Formulary as a prescribing note. FC July 2008 'Not preferred' as a suitable alternative exists. FC Novemeber 2010

Date SMC Recommendation *Report number*	Product ***Manufacturer*** ***Indication***	SMC Recommendation For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Formulary Committee Comments For more details see www.ljf.scot.nhs.uk
14.01.13 *SMC Report No 826/12*	vildagliptin 50mg tablets (Galvus®) *Novartis* *Treatment of type 2 diabetes mellitus in adults as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.*	Restricted use: vildagliptin (Galvus®) is accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus in adults as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. SMC restriction: for use in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance. In two comparator controlled studies the non-inferiority of vildagliptin to first-line oral anti-diabetic agents was not shown. A network meta-analysis demonstrated similar reductions in HbA1c at 24 weeks for vildagliptin versus another dipeptidyl peptidase 4 (DPP-4) inhibitor.	**Not included** on the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. LJF choice is sitagliptin. FC March 2013
09.12.13 *SMC Report No. 875/13*	vildagliptin 50mg tablets (Galvus®) *Novartis Europharm Limited* *Treatment of type 2 diabetes mellitus in adults as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.*	Restricted use: vildagliptin (Galvus®) is accepted for restricted use within NHS Scotland for the treatment of type 2 diabetes mellitus in adults as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. SMC restriction: as an alternative dipeptidyl peptidase-4 inhibitor option. Treatment with vildagliptin reduces HbA1c levels significantly more than placebo when used in combination with metformin and a sulphonylurea. A Bayesian network meta-analysis suggested similar efficacy to another dipeptidyl peptidase-4 inhibitor.	**Not included** on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. FC January 2014
13.05.13 *SMC Report No. 874/13* NON SUBMISSION	vildagliptin/metformin hydrochloride (Eucreas®) 50mg/850mg and 50mg/1000mg film-coated tablets *Novartis Pharmaceuticals UK Ltd* *Treatment of type 2 diabetes mellitus.*	NOT RECOMMENDED: vildagliptin/metformin hydrochloride (Eucreas®) is not recommended for use within NHS Scotland for the treatment of type 2 diabetes mellitus: • in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea • in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control The holder of the marketing authorisation has not made a submission to SMC regarding this product in these indications. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
07.03.11 *SMC Report No. 686/11*	vinflunine ditartrate 25mg/ml concentrate for solution for infusion (Javlor®) *Pierre Fabre Ltd* *As monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen. Efficacy and safety of vinflunine have not been studied in patients with performance status ≥2.*	NOT RECOMMENDED: vinflunine (Javlor®) is not recommended for use within NHS Scotland. Indication under review: monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract (TCCU) after failure of a prior platinum-containing regimen. Vinflunine plus best supportive care was associated with improved survival when compared to best supportive care alone in the second-line treatment of advanced or metastatic TCCU in patients with good performance status. However, the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED

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13.06.05 *SMC Report No. 179/05*	vinorelbine 20 and 30mg capsules (Navelbine® Oral) *Pierre Fabre Ltd* *As a single agent or in combination for the first line treatment of stage III or IV non-small-cell lung cancer.*	Restricted use: vinorelbine capsule (Navelbine®Oral) is accepted for restricted use within NHS Scotland for the first line treatment of stage lll or IV non-small-cell lung cancer. It is restricted to use by specialist oncologists as an alternative to the intravenous formulation of vinorelbine. It is more expensive than the intravenous formulation of vinorelbine. However, its use may allow changes to service delivery that have individual patient or organisational benefits.	'Not preferred' in Lothian. FC July 2007
13.08.07 *SMC Report No. 324/06* PRODUCT UPDATE (abbreviated submission)	vinorelbine 20mg and 30mg capsule (Navelbine®) *Pierre Fabre Ltd* *Treatment of advanced breast cancer stage III and IV relapsing after, or refractory to, an anthracycline-containing regimen.*	Restricted use: Vinorelbine capsule (Navelbine®) is accepted for restricted use within NHS Scotland for treatment of advanced breast cancer stage III and IV relapsing after, or refractory to, an anthracycline-containing regimen. It is restricted to use by specialist oncologists as an alternative to the intravenous formulation of vinorelbine where vinorelbine is considered to be appropriate. It is more expensive than the intravenous formulation of vinorelbine. However, its use may allow changes to service delivery that have individual patient or organisational benefits.	Added to the Additional List, for Specialist Use only. FC July 2008
07.10.13 *SMC Report No. 924/13* NON SUBMISSION	vismodegib (Erivedge®) 150 mg hard capsules *Roche Products Ltd* *Treatment of adult patients with:* • *symptomatic metastatic basal cell carcinoma* • *locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy*.	NOT RECOMMENDED: vismodegib (Erivdege®) is not recommended for use within NHS Scotland for the treatment of adult patients with: • symptomatic metastatic basal cell carcinoma • locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.01.03 *SMC Report No. 25/02*	voriconazole (VFEND®) *Pfizer Limited* *Only in suspected or confirmed cases of invasive aspergillosis; for infections caused by Fusarium spp and Scedosporium spp; or serious invasive candidiasis refractory to fluconazole.*	Restricted use: voriconazole should be used only in suspected or confirmed cases of invasive aspergillosis; for infections caused by *Fusarium spp* and *Scedosporium spp*; or serious invasive candidiasis refractory to fluconazole. It should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections.	Added to the Additional List. Specialist use only. FC August 2004
13.12.04 *SMC Report No. 142/04* PRODUCT UPDATE (abbreviated submission)	voriconazole (VFEND®) *Pfizer Limited* *only in suspected or confirmed cases of invasive aspergillosis; for infections caused by Fusarium spp and Scedosporium spp; or serious invasive candidiasis refractory to fluconazole.*	Restricted use: voriconazole (VFEND®) as a powder for oral suspension (40mg/ml) is accepted for restricted use in NHS Scotland. As previously stated by SMC (January 2003), voriconazole should be used only in suspected or confirmed cases of invasive aspergillosis; for infections caused by *Fusarium spp* and *Scedosporium spp*; or serious invasive candidiasis refractory to fluconazole. It should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections. The oral bio-availability of voriconazole is almost complete, allowing patients to be switched between intravenous and oral therapy, and the oral liquid formulation of voriconazole provides an alternative for patients who cannot take tablets. The cost per day is similar to that with tablets, and markedly less than with infusion.	Added to the Additional List. Specialist use only. FC February 2005

Date SMC Recommendation ***Report number***	**Product** ***Manufacturer*** ***Indication***	**SMC Recommendation** **For more details see www.scottishmedicines.org.uk**	**Lothian Recommendation and Formulary Committee Comments** **For more details see www.ljf.scot.nhs.uk**
05.08.05 *SMC Report No. 194/05*	voriconazole 50mg, 200mg tablets, 40mg/ml oral suspension, 200mg vials for infusion (Vfend®) *Pfizer Limited* *Candidaemia in non-neutropenic patients.*	Restricted use: voriconazole (Vfend®) is accepted for restricted use within NHS Scotland for the treatment of candidaemia in non-neutropenic patients. Voriconazole provides an additional agent for the treatment of candidaemia in non-neutropenic patients. Its use is restricted to patients with fluconazole-resistant Candida infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at an increased risk of serious side-effects with amphotericin.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication. FC April 2008
08.10.07 SMC Report No. 405/07	ziconotide, 100micrograms/mL solution for intrathecal infusion (Prialt®) *Eisai Ltd* *Treatment of severe, chronic pain in patients who require intrathecal analgesia.*	NOT RECOMMENDED: ziconotide (Prialt®) is not recommended for use within NHS Scotland for the treatment of severe, chronic pain in patients who require intrathecal analgesia. Ziconotide, compared to placebo, improved pain scores in patients with chronic severe intractable pain despite treatment with systemic and/or intrathecal analgesia. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED
12.01.04 *SMC Report No. 29/02* FOLLOWING INDEPENDENT REVIEW PANEL ASSESSMENT	zoledronic acid (Zometa®) *Novartis Europharm Ltd* *Prevention of skeletal related events (SREs) in patients with advanced prostate cancer involving bone.*	NOT RECOMMENDED: zoledronic acid (Zometa®) is not recommended for use within NHS Scotland for the prevention of skeletal related events (SREs) in patients with advanced prostate cancer involving bone. Although zoledronic acid demonstrated a reduction in SREs compared with placebo in these patients, the absolute reduction was small and the study requires caution in accepting this as sufficient evidence to introduce zoledronic acid into standard practice for the treatment of patients with metastatic prostate cancer. An economic case was submitted by the manufacturer but its quality was not judged to be sufficient to support a recommendation that the drug is cost effective relative to standard practice in Scotland for this particular indication.	NOT RECOMMENDED
09.10.06 *SMC Report No. 317/06*	zoledronic acid 5mg/100ml solution for infusion (Aclasta®) *Novartis* *Treatment of Paget's disease of bone in patients for whom the use of a bisphosphonate is appropriate.*	Accepted for use: zoledronic acid 5mg (Aclasta®) is accepted for use within NHS Scotland for the treatment of Paget's disease of bone in patients for whom the use of a bisphosphonate is appropriate. Zoledronic acid infusion resulted in similar levels of pain relief but greater and more sustained reduction of serum alkaline phosphatase (a marker of bone turnover) than one course of an oral bisphosphonate.	Added to the Additional List, for Specialist Use only. FC October 2006
10.03.08 *SMC Report No. 447/08*	zoledronic acid, 5 mg solution for infusion (Aclasta®) *Novartis Pharmaceuticals UK Limited* *Treatment of osteoporosis in post-menopausal women at increased risk of fractures.*	Restricted use: zoledronic acid 5mg solution for infusion (Aclasta®) is accepted for restricted use within NHS Scotland for treatment of osteoporosis in post-menopausal women at increased risk of fractures. Intravenous zoledronic acid is restricted to use in patients who are unsuitable for or unable to tolerate oral treatment options for osteoporosis. Treatment initiation should be under specialist supervision. This preparation is licensed for administration once a year and has been shown to reduce the incidence of vertebral and hip fractures over 3 years compared with placebo.	Added to the Formulary as prescribing note – specialist use only FC June 2008.
12.01.09 *SMC Report No. 535/08* NON SUBMISSION	zoledronic acid 5mg/100ml solution for infusion (Aclasta®) *Novartis Pharmaceuticals UK Ltd* *The treatment of osteoporosis in men at increased risk of fracture, including those with a recent low-trauma hip fracture.*	NOT RECOMMENDED: zoledronic acid 5mg (Aclasta®) is not recommended for use within NHS Scotland for the treatment of osteoporosis in men at increased risk of fracture, including those with a recent low-trauma hip fracture. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED

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12.12.05 *SMC Report No. 216/05*	zonisamide hard capsules 25mg, 50mg, 100mg (Zonegran®) *Eisai Ltd* *Adjunctive therapy in adult patients with partial seizures, with or without secondary generalisation.*	Restricted use: zonisamide (Zonegran®) is accepted for restricted use within NHS Scotland as adjunctive therapy in adult patients with partial seizures, with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older ant-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.	Added to the Additional List, for specialist initiation or on specialist advice. FC April 2008
08.10.12 *SMC Report No. 817/12* NON SUBMISSION	zonisamide (Zonegran®) 25, 50, 100mg Hard Capsules *Eisai Ltd* *Monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy.*	NOT RECOMMENDED: zonisamide (Zonegran®) is not recommended for use within NHS Scotland as monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED
10.03.14 *SMC Report No. 949/14* PRODUCT UPDATE (abbreviated submission)	zonisamide 25mg, 50mg and 100mg capsules (Zonegran®) *Eisai Limited* *As adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above.*	Restricted use: zonisamide (Zonegran®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above. SMC restriction: on advice from specialists (paediatric neurologists or paediatricians with an expertise in epilepsy). The Scottish Medicines Consortium has previously accepted zonisamide for restricted use in adult patients with partial seizures, with or without secondary generalisation. It was restricted to initiation by physicians with appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.	**Included** on the Additional List, for Specialist Use only, for the indication in question. FC February 2014