Drugs NOT RECOMMENDED by the Scottish Medicines Consortium (SMC) - up to and including June 2014

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**
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
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
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

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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
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
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

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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
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
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
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

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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
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
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
13.02.12 *SMC Report No. 753/12*	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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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
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 a 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 a 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
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

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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
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
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
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

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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
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

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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
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
08.08.11 *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

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. 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
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
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
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

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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
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**
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
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. Clinical effectiveness has not been demonstrated in the patient population under consideration in the resubmission.	NOT RECOMMENDED
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
11.04.11 *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

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08.11.10 *SMC Report No. 658/10* NON SUBMISSION	canakinumab (Ilaris®) 150 mg/ml, powder for solution for injection intended *Novartis Pharmacuticals* *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
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

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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
07.08.06 *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
07.03.03 *SMC Report No. 30/03*	caspofungin acetate (Cancidas®) *Merck Sharpe & Dohme Ltd* *Invasive aspergillosis.*	NOT RECOMMENDED: 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
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
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

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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
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
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
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
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

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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 NHSScotland 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 NHSScotland.	NOT RECOMMENDED
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
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

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. 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 NHSScotland 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 NHSScotland.	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
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

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**
13.07.10 *SMC Report No. 633/10* NON SUBMISSION	corifollitropin alfa (Elonva®) 100 and 150mcg solution for injection *MSD* *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 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
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
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
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 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
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

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. 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
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
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
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
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

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. 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
07.11.05 *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
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
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
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
13.10.08 *SMC Report No. 514/08* NON SUBMISSION	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

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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
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
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
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
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

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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
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
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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED

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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
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
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
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
07.03.11 *SMC Report No. 23/03* 2nd 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

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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
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
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
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

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
08.07.13 *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
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
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
13.01.14 *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

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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 NHS Scotland.	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 NHS Scotland.	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
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
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
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

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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
08.08.11 *SMC Report No: 729/11* NONSUBMISSION	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
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

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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
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
12.10.09 *SMC Report No. 582/09* NONSUBMISSION	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
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
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

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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 NHS Scotland 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 NHS Scotland.	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 NHS Scotland 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 NHS Scotland.	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 NHS Scotland 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 NHS Scotland.	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 NHS Scotland 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 NHS Scotland.	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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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

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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
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
10.10.11 *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
11.09.06 *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

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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
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
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

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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
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
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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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

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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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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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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
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
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
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

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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®) as 150 mg and 300mg tablets 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
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
09.01.04 *SMC Report No. 57/03* RESUBMISSION	memantine (Ebixa®) *Lundbeck Ltd* *Moderately severe to severe Alzheimer's disease.*	NOT RECOMMENDED: memantine (Ebixa®) is not recommended for use within NHS Scotland. This is currently the only agent licensed in UK for use in moderately severe to severe Alzheimer's disease. There is only one pivotal trial and it involves 252 patients. It showed a statistically significant benefit over placebo of 0.3 in the Clinician's Interview Based Impression of Change (CIBIC+) on a scale of 1-7, which includes care givers' views. It also showed a reduction in the Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory (ADCS-ADL) of 3.4 on a 54 point range. These results show that the magnitude of any effect is small, the clinical importance of which is unclear. No target sub group of the population could be identified as potential responders nor was there evidence of an optimal duration of treatment. The economic case submitted by the manufacturer does not support a recommendation that use of this drug would be cost effective relative to standard practice in Scotland.	NOT RECOMMENDED
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

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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
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
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

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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
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
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
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

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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
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
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
09.08.10 *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

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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
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
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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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
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 NHS Scotland.	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
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
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

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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
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
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

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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
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 NHS Scotland.	NOT RECOMMENDED
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

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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
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
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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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

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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
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

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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
12.11.12 *SMC Report No. 565/09* INDEPENDEND 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

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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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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
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
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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED

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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
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
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
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
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*	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

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08.06.09 *SMC Report No. 558/09* NONSUBMISSION	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
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
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
10.11.03 *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
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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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.
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 SQ-T 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
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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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
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
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
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
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

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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
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 NHS Scotland.	NOT RECOMMENDED
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
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
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

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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
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
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
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

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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 NHS Scotland.	NOT RECOMMENDED

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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
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 NHS Scotland 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 NHS Scotland.	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 NHS Scotland 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 NHS Scotland.	NOT RECOMMENDED
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
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

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
11.08.08 *SMC Report No. 501/08*	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 NHS Scotland 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 NHS Scotland	NOT RECOMMENDED
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
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
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

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**
12.01.04 *SMC Report No. 29/02* 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
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
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