NHS Borders: New Medicines Decisions APRIL 2016 – MARCH 2017

Please note: We are happy to consider requests for other languages or formats. Please contact Pharmacy Admin Office kate.warner@borders.scot.nhs.uk

In Scotland, a newly licensed medicine is routinely available in a health board only after it has been:

- accepted for use in NHSScotland by the Scottish Medicines Consortium (SMC), and
- accepted for use by the health board's Area Drug and Therapeutics Committee (ADTC).

All medicines accepted by SMC are available in Scotland, but may not be considered 'routinely available' within a particular health board because of available services and preferences for alternative medicines. 'Routinely available' means that a medicine can be prescribed by the appropriately qualified person within a health board.

Each health board has an ADTC. The ADTC is responsible for advising the health board on all aspects of the use of medicines.
Medicines routinely available within a health board are usually included in the local formulary. The formulary is a list of medicines for use in the health board that has been agreed by ADTC in consultation with local clinical experts. It offers a choice of medicines for healthcare professionals to prescribe for common medical conditions. A formulary can help improve safety as prescribers are likely to become more familiar with the medicines in it and also helps make sure that standards of care are consistent across the health board.

How does the health board decide which new medicines to make routinely available for patients?
The ADTC in a health board will consider national and local guidance before deciding whether to make a new medicine routinely available.

What national guidance does the ADTC consider?

- SMC advice: The SMC considers newly licensed medicines and advises health boards in Scotland whether they should be available. When SMC considers a new medicine for the NHS in Scotland, it looks at:
  - how well the medicine works,
  - which patients might benefit from it ,
  - whether it is as good or better than medicines the NHS already uses to treat the medical condition, and
  - whether it is good value for money.

  In the table below, national guidance usually refers to SMC advice. Links to SMC advice for individual medicines are also included in the table.
- In some cases, other agencies may also provide guidance on how medicines should be used. For example, Healthcare Improvement Scotland issues alerts to advise if National Institute for Health and Care Excellence Multiple Technology Appraisals (NICE MTAs) are applicable in Scotland.

What local guidance does the ADTC consider?

- Advice from local clinical experts who would be expected to prescribe a particular medicine, where that service is available in a health board.

Why is a particular medicine not routinely available in my health board?

- This is usually because the medicine is not recommended for use in NHSScotland by the SMC.
- The medicine may not be routinely available in a health board, particularly in smaller health boards, because there is not a suitable specialist who may use the medicine.
- There may also be differences in which medicines are preferred in health boards. Sometimes SMC accepts more than one medicine for treating a specific medical condition. Clinical experts in each health board consider whether to add new medicines to their formulary and advise the ADTC. Sometimes it is agreed that established medicines are a better choice than new medicines.

What happens if a particular medicine is not routinely available in my health board?

- If a medicine is not routinely available and included on your health board's formulary and there are no suitable alternatives on the formulary, a healthcare professional can request to prescribe a medicine that is not on the formulary if they think you will benefit from using it. All health boards have procedures in place to consider requests when a healthcare professional feels a medicine that is not on the formulary would be right for a particular patient.

NHS Borders board decisions – six options:

- Routinely available in line with national guidance (link to SMC advice)
- Routinely available in line with local guidance for prescribing (link, if desired, to local or regional guidance)
- Routinely available from a specialist centre in another NHS board
- Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice)
- Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local or regional guidance)
- Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by *(enter date)*

The following table lists NHS Borders decisions on new medicines, ordered by MONTH of decision and then A-Z.
If you need more information on medicines decisions in NHS Borders, please email Formulary Pharmacist liz.leitch@borders.scot.nhs.uk.

APRIL 2016				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Alendronic Acid Binosto® 1137/16	Advice following an abbreviated submission: **Alendronic acid effervescent tablets (Binosto®)** is accepted for restricted use within NHS Scotland. Indication under review: Treatment of postmenopausal osteoporosis. SMC restriction: for use in patients who are unable to swallow tablets where alendronic acid is the appropriate treatment choice. Alendronic acid 70mg effervescent tablets have demonstrated bioequivalence to alendronic acid 70mg tablets. The effervescent tablet formulation provides an alternative for patients who cannot swallow tablets. It is more expensive than generic alendronic acid tablets but is similar to the cost of existing oral solutions.	11.04.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1137_16_alendronic_acid_Binosto/alendronic_acid_Binosto_ABBREVIATED	13.04.2016
Ataluren Translarna® 1131/16	Advice following a full submission considered under the ultra-orphan process: **Ataluren (Translarna®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older. In a phase IIb, randomised, double-blind study the absolute difference in mean change in 6-minute walking distance from baseline to week 48 for ataluren 40mg/kg/day compared to placebo was 30 metres in the intent-to-treat analysis. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	11.04.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1131_16_ataluren_Translarna/ataluren_Translarna	13.04.2016
Camellia Sinensis (green tea) leaf Catephen® 1133/16	Advice following a full submission: **Camellia sinensis (green tea) leaf extract (Catephen®)** is accepted for restricted use within NHS Scotland. Indication under review: Cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years. SMC restriction: for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin. Complete clearance of baseline and new warts was achieved in a significantly higher proportion of patients treated for up to 16 weeks with camellia sinensis (green tea) 10% ointment than vehicle ointment, in two phase III randomised double-blind studies.	11.04.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1133_16_camellia_sinensis_green_tea_leaf_Catephen/camellia_sinensis_green_tea_leaf_Catephen	13.04.2016

Eculizumab Soliris® 1130/16	Advice following a full submission assessed under the ultra orphan process: **Eculizumab (Soliris®)** is not recommended for use within NHS Scotland. Indication under review: In adults and children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history. In a controlled study in patients with transfusion-dependent PNH, eculizumab reduced the rate of haemolysis and improved anaemia compared with placebo. Observational data from a subset of the PNH registry suggest that these benefits may also be achieved in patients with no history of transfusions. Uncontrolled data suggest that eculizumab reduces the incidence of thrombosis in patients with PNH. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	11.04.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1130_16_eculizumab_Soliris_PNH/eculizumab_Soliris_for_PNH	13/04/2016
Everolimus Afinitor® 872/13	Advice following a second resubmission assessed under the end of life process: **Everolimus (Afinitor®)** is accepted for use within NHS Scotland. Indication under review: For the treatment of hormone receptor-positive, 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. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	11.04.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/872_13_everolimus_Afinitor/everolimus_Afinitor_2nd_RESUBMISSION	13.04.2016
Isavuconazole Cresemba® 1129/16	Advice following a full submission considered under the orphan process: **Isavuconazole (Cresemba®)** is accepted for use within NHS Scotland. Indication under review: in adults for the treatment of: • invasive aspergillosis; • mucormycosis in patients for whom amphotericin B is inappropriate. A phase III, randomised, double-blind, non-inferiority study demonstrated that, in the treatment of	11.04.2016	Routinely available in line with national guidance. http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1129_16_isavuconazole_Cresemba/isavuconazole_Cresemba	13.04.2016

	invasive aspergillosis, isavuconazole was non-inferior to a triazole antifungal for all-cause mortality through day 42, and had a similar overall response at the end of treatment. A phase III, open-label, single-arm study demonstrated that, in the treatment of mucormycosis, isavuconazole had a treatment effect on all-cause mortality and overall response. The treatment effect was considered to be comparable to that observed in external control studies of a polyene antifungal. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of isavuconazole. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			

MAY 2016				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Adalimumab Humira 1143/16	Advice following a full submission: **Adalimumab (Humira®)** is accepted for use within NHS Scotland. Indication under review: treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. Evidence from two double-blind, randomised studies demonstrated significant reductions in inflammatory lesions and no worsening of abscesses and draining fistulas at 12 weeks with adalimumab compared with placebo.	09.05.2016	Available in line with local guidance for prescribing http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1143_16_adalimumab_Humira/adalimumab_Humira	08.06.2016
Bevacizumab Avastin 1135/16	Advice following a full submission considered under the end of life and ultra orphan medicine process: **Bevacizumab (Avastin®)** is accepted for restricted use within NHS Scotland. Indication under review: in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. Restriction: for use in combination with cisplatin and paclitaxel. In an open-label, randomised, phase III study, the addition of bevacizumab to combination chemotherapy increased overall survival. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of bevacizumab. This advice is contingent upon the continuing availability of the patient	09.05.2016	Routinely available in line with national guidance *http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1135_16_bevacizumab_Avastin/bevacizumab_Avastin*	08.06.2016

	access scheme in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.			
Ceftolozane-Tazobactam Zerbaxa 1146/16	Advice following a full submission: **Ceftolozane/ tazobactam (Zerbaxa®)** is not recommended for use within NHS Scotland. Indication under review: for the treatment of the following infections in adults: - Complicated intra-abdominal infections; - Acute pyelonephritis; - Complicated urinary tract infections. In a phase III, randomised, double-blind study, ceftolozane/ tazobactam, in combination with metronidazole, demonstrated non-inferior efficacy to a carbapenem in patients with complicated intra-abdominal infections.In a phase III, randomised, double-blind study, ceftolozane/tazobactam demonstrated non-inferior efficacy to a quinolone antibiotic in patients with acute pyelonephritis or complicated urinary tract infections.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 clinical and economic analysis to gain acceptance by SMC.	09.05.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1146_16_ceftolozane_tazobactam_Zerbaxa/ceftolozane_tazobactam_Zerbaxa	08.06.2016
Certolizumab Pegol Cimzia 1155/16	Advice in the absence of a submission from the holder of the marketing authorisation: **Certolizumab pegol (Cimzia®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. 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.	09.05.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1155_16_certolizumab_pegol_Cimzia/certolizumab_pegol_Cimzia	08.06.2016
Elvitegravir / Cobicistat / Emtricitabine / Tenofovir Alafenamide Fumarate Genvoya 1142/16	Advice following a full submission: **Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide film-coated tablet (Genvoya®)** is accepted for use within NHS Scotland. Indication under review: the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir. In two phase III, randomised, double-blind studies (in treatment-naïve adults with HIV-1), and one phase III, randomised, open-label study (in treatment-experienced adults with HIV-1), Genvoya® was non-inferior to alternative antiretroviral regimens at achieving/maintaining a high rate of viral suppression (plasma HIV-1 RNA <50 copies/mL) at week 48. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Genvoya®. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list	09.05.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1142_16_elvitegravir_cobicistat_emtricitabine_tenofovir_alafenamide_fumarate_Genvoya/elvitegravir_cobicistat_emtricitabine_tenofovir_alafenamide_fumarate_Genvoya	08.06.2016

	price that is equivalent or lower.			
Ivacaftor granules Kalydeco 1134/16	Advice following a full submission assessed under the ultra orphan medicine process: **Ivacaftor (Kalydeco®)** is not recommended for use within NHS Scotland. Indication under review: treatment of children with cystic fibrosis (CF) aged 2 years and older and weighing less than 25kg who have one of the following gating (class III) mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R. In an open-label single-arm study, acceptable safety was demonstrated in children aged 2 to 5 years. 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 clinical and economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	09.05.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1134_16_ivacaftor_Kalydeco/ivacaftor_Kalydeco	08.06.2016
Lumacaftor-Ivacaftor Orkambi 1136/16	Advice following a full submission considered under the orphan medicine process: **Lumacaftor, ivacaftor (Orkambi®)** is not recommended for use within NHS Scotland. Indication under review: treatment of cystic fibrosis (CF) in patients aged 12 years and older who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. Lumacaftor-ivacaftor, compared to placebo, significantly increased percent predicted forced expiratory volume in one second (ppFEV1) by less than 3% at six months and reduced the annual rate of pulmonary exacerbations in patients with CF homozygous for the F508del mutation of the CFTR gene. 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 clinical and economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	09.05.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1136_16_lumacaftor_ivacaftor_Orkambi/lumacaftor_ivacaftor_Orkambi	08.06.2016
Ramucirumab Cyrmaza 1156/16	Advice in the absence of a submission from the holder of the marketing authorisation: **Ramucirumab (Cyramza®)** is not recommended for use within NHS Scotland. Indication under review: in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) for the treatment of adult patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. 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	09.05.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1156_16_ramucirumab_Cyrmaza/ramucirumab_Cyramza	08.06.2016

	NHSScotland.			

JUNE 2016				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Blinatumomab Blincyto® 1145/16	Advice following a full submission assessed under the end of life and ultra orphan processes **Blinatumomab (Blincyto®)** is accepted for use within NHS Scotland. Indication under review: The treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). In a non-comparative phase II study of patients with relapsed or refractory Philadelphia chromosome-negative B-precursor ALL, blinatumomab was associated with clinically relevant complete remission rates. Controlled data with clinical outcomes are currently lacking. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of blinatumomab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	13.06.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1145_16_blinatumomab_Blincyto/blinatumomab_Blincyto	13.07.2016
Cabazitaxel Jevtana® 735/11	Advice following a resubmission considered under the end of life process **Cabazitaxel (Jevtana®)** is not recommended for use within NHS Scotland. Indication under review: cabazitaxel, in combination with prednisone or prednisolone, is indicated 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/ prednisolone was associated with an extended median overall survival of 2.4 months compared with an alternative chemotherapy regimen.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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The licence holder has indicated their intention to resubmit.	13.06.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/735_11_cabazitaxel_Jevtana/cabazitaxel_Jevtana_Re_submission	13.07.2016
Co-careldopa-levodopa	Advice following a 2nd resubmission assessed under the orphan process **Co-careldopa (Duodopa®)** intestinal gel is accepted for	13.06.2016	Not routinely available as local implementation plans are being developed or	13.07.2016

Duodopa® 316/06	restricted use within NHS Scotland. Indication under review: 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. SMC restriction: for use in patients not eligible for deep brain stimulation. In a phase III, 12-week study, co-careldopa intestinal gel significantly reduced 'off' time compared with oral levodopa plus a dopa decarboxylase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of co-careldopa intestinal gel. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.		the ADTC is waiting for further advice from local clinical experts http://www.scottishmedicines.org.uk/SMC_Advice/Advice/316_06_co_careldopa_Duodopa/co_careldopa_levodopa_Duodopa_2nd_Resubmission	
Eltrombopag olamine Revolade® 1164/16	Advice in the absence of a submission from the holder of the marketing authorisation **Eltrombopag olamine (Revolade®)** is not recommended for use within NHS Scotland. Indication under review: Treatment in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	13.06.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1164_16_eltrombopag_olamine_Ravolade/eltrombopag_olamine_Revolade_Non_submission	13.07.2016
Evolocumab Repatha® 1148/16	Advice following a full submission **Evolocumab (Repatha®)** is not recommended for use within NHS Scotland. Indication under review: In adults with primary hypercholesterolaemia (heterozygous familial hyper-cholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or,; • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated; • In adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies. In phase III clinical studies, treatment with evolocumab added to optimised background lipid-lowering therapy significantly improved mean percentage change in LDL-C from baseline to week 12, versus placebo and another lipid-lowering treatment, in patients with heterozygous familial and non-familial hypercholesterolaemia and mixed dyslipidaemia. Addition of	13.06.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1148_16_evolocumab_Repatha/evolocumab_Repatha	13.07.2016

	evolocumab to standard care also significantly reduced LDL-C versus standard care alone in patients with homozygous familial hypercholesterolaemia. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.			
Febuxostat Adenuric® 1153/16	Advice following a full submission **Febuxostat film-coated tablet (Adenuric®)** is accepted for restricted use within NHS Scotland. Indication under review: the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS). SMC restriction: prevention of hyperuricaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated, such as: • Those intolerant of allopurinol; • Those in whom allopurinol is contraindicated, e.g. patients with renal impairment. In a phase III, randomised, double-blind study in adults with haematologic malignancies at intermediate to high risk of TLS, febuxostat was significantly superior to a xanthine oxidase inhibitor at reducing serum uric acid levels.	13.06.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1153_16_febuxostat_Adenuric/febuxostat_Adenuric	13.07.2016
Mepolizumab Nucala® 1149/16	Advice following a full submission **Mepolizumab (Nucala®)** is accepted for restricted use within NHS Scotland. Indication under review: as an add-on treatment for severe refractory eosinophilic asthma in adult patients. SMC restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15 x 109/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids. Mepolizumab, compared to placebo, decreased the incidence of asthma exacerbations and permitted reductions in doses of maintenance oral corticosteroid in adult patients with severe eosinophilic asthma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mepolizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	13.06.2016	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1149_16_mepolizumab_Nucala/mepolizumab_Nucala	13.07.2016
Naproxen Stirlescent® 1154/16	Advice following an abbreviated submission **Naproxen 250mg effervescent tablets (Stirlescent®)** are accepted for restricted use within NHS Scotland. Indication under review: treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults. SMC restriction: use in patients unable to swallow naproxen tablets. Naproxen 250mg effervescent tablets (Stirlescent®) have demonstrated bioequivalence to naproxen 250mg tablets. The	13.06.2016	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1154_16_naproxen_Stirlescent/naproxen_Stirlescent	13.07.2016

	effervescent tablet formulation provides an alternative for patients who cannot swallow tablets. They are more expensive than generic naproxen tablets but cost less than unlicensed naproxen oral liquid (special formulation). Another non-steroidal anti-inflammatory drug is available in dispersible form and may cost less than naproxen when the higher dose of naproxen is required.			
Ramucirumab Cyramza® 1165/16	Advice in the absence of a submission from the holder of the marketing authorisation **Ramucirumab (Cyramza®)** is not recommended for use within NHS Scotland. Indication under review: in combination with docetaxel for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based 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.	13.06.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1165_16_ramucirumab_Cyramza/ramucirumb_Cyramza	13.07.2016
Ruxolitinib [as phosphate] Jakavi® 1166/16	Advice in the absence of a submission from the holder of the marketing authorisation **Ruxolitinib phosphate (Jakavi®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. 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.	13.06.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1166_16_ruxolitinib_as_phosphate_Jakavi/ruxolitinib_Jakavi_Non_submission	13.07.2016

JULY 2016

Medicine	Condition being treated	Date SMC Advice Published	NHS BORDERS decision	Date NHSB Decision
Adalimumab Humira® 1173/16	Advice in the absence of a submission from the holder of the marketing authorisation **Adalimumab (Humira®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy. (This licence extension relates to previous SMC advice (468/08). SMC has previously accepted adalimumab for restricted use for the treatment of chronic plaque psoriasis in adult patients who failed to respond to or have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. It is restricted to patients with severe disease as defined by a total Psoriasis Area Severity Index score	11.07.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1173_16_adalimumab_Humira/adalimumab_Humira	13.07.2016

	of ≥10 and a Dermatology Life Quality Index of >10. (SMC 468/08). This advice remains valid. 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.			
Afatinib Giotrif® 1174/16	Advice in the absence of a submission from the holder of the marketing authorisation **Afatinib (Giotrif®)** is not recommended for use within NHS Scotland. Indication under review: As monotherapy for the treatment of locally advanced or metastatic non small cell lung cancer of squamous histology progressing on or after platinum-based chemotherapy. 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.	11.07.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1174_16_afatinib_Giotrif/afatinib_Giotrif	13.07.2016
Azacitidine Vidaza® 1175/16	Advice in the absence of a submission from the holder of the marketing authorisation **Azacitidine (Vidaza®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients aged 65 years or older who are not eligible for haematopoietic stem cell transplantation (HSCT) with acute myeloid leukaemia (AML) with >30% marrow blasts according to the World Health Organisation (WHO) classification. 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.	11.07.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1175_16_azacitidine_Vidaza/azacitidine_Vidaza	13.07.2016
Brivaracetam Briviact 1160/16	Advice following a full submission **Brivaracetam (Briviact®)** is accepted for restricted use within NHS Scotland. Indication under review: Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. SMC restriction: for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy. In a pooled analysis of three fixed-dose, placebo-controlled, phase III studies there were statistically significant reductions in the frequency of partial-onset seizures with brivaracetam versus placebo.	11.07.2016	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1160_16_brivaracetam_Briviact/brivaracetam_Briviact	13.07.2016
Crizotinib Xalkori® 1152/16	Advice following a full submission under the end of life and ultra-orphan process **Crizotinib (Xalkori®)** is accepted for use within NHS Scotland. Indication under review: First-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). In patients with previously untreated advanced ALK-positive NSCLC, crizotinib significantly improved progression-free survival compared with a standard systemic anti-	11.07.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1152_16_crizotinib_Xalkori/crizotinib_Xalkori	13.07.2016

	cancer therapy. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Nivolumab Opdivo 1144/16	Advice following a full submission assessed under the end of life process **Nivolumab (Opdivo®)** is accepted for use within NHS Scotland. Indication under review: Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. Nivolumab, compared with a standard second-line chemotherapy, significantly increased overall survival in patients with locally advanced or metastatic squamous NSCLC who had received previous therapy including platinum-based doublet chemotherapy. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	11.07.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1144_16_nivolumab_Opdivo_for_metastatic_squamous_NSCLC/nivolumab_Opdivo_for_metastatic_squamous_NSCLC	13.07.2016
Ramucirumab Cyramza® 1176/16	Advice in the absence of a submission from the holder of the marketing authorization **Ramucirumab (Cyramza®)** is not recommended for use within NHS Scotland. Indications under review: • In combination with paclitaxel for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy • As monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate 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.	11.07.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1176_16_ramucirumab_Cyramza/ramucirumab_Cyramza	13.07.2016
Secukinumab Cosentyx 1159/16	Advice following a full submission **Secukinumab (Cosentyx®)** is accepted for use within NHS Scotland. Indication under review: Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy. Secukinumab, compared with placebo, significantly improved symptoms of AS in adults with active disease	11.07.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1159_16_secukinumab_Cosentyx_AS/secukinumab_Cosentyx	13.07.2016

	inadequately controlled with non-steroidal anti-inflammatory drugs. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Vortioxetine Brintellix 1158/16	Advice following a full submission **Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®)** is accepted for restricted use within NHS Scotland. Indication under review: the treatment of major depressive episodes in adults. SMC restriction: patients who have experienced an inadequate response (either due to lack of adequate efficacy and/or safety concerns/intolerability) to two or more previous antidepressants. In two phase III, randomised, double-blind studies in adults with major depressive disorder, vortioxetine was non-inferior to two alternative antidepressants at reducing the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to week 8.	11.07.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1158_16_vortioxetine_Brintellix/vortioxetine_Brintellix	13.07.2016

AUGUST 2016

Medicine	Condition being treated	Date SMC Advice Published	NHS BORDERS decision	Date NHSB Decision
Alirocumab Praluent 1147/16	Advice following a full submission **alirocumab (Praluent®)** is accepted for restricted use within NHS Scotland. Indication under review: adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. • SMC restriction: for specialist use only in patients at high cardiovascular risk as follows: • patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, • patients with HeFH and LDL-C ≥3.5mmol/L, for secondary prevention of cardiovascular events or, • patients at high risk due to previous cardiovascular events	08.08.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1147_16_alirocumab_Praluent/alirocumab_Praluent	10.08.2016

	and LDL-C ≥4.0mmol/L or, • patients with recurrent/polyvascular disease and LDL-C ≥3.5mmol/L. In a large phase III clinical study program, alirocumab significantly reduced LDL-C from baseline to week 24 versus active and placebo comparators in patients with hypercholesterolaemia unable to reach lipid goals with currently available therapies. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of alirocumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Diamorphine hydrochloride Ayendi 1172/16	Advice following an abbreviated submission **Diamorphine hydrochloride (Ayendi®)** is accepted for use within NHS Scotland. Indication under review: treatment of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray (Ayendi®) should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring. Unlicensed intranasal diamorphine has been used in the NHS in Scotland for the treatment of severe pain in children in the emergency setting. The availability of diamorphine hydrochloride nasal spray (Ayendi®) provides a licensed preparation.	08.08.2016	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this timehttp://www.scottishmedicines.org.uk/SMC_Advice/Advice/1172_16_diamorphine_hydrochloride_Ayendi/diamorphine_hydrochloride_Ayendi	10.08.2016
Elotuzumab Empliciti 1183/16	Advice in the absence of a submission from the holder of the marketing authorisation **elotuzumab (Empliciti ®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in adult patients who have received at least one prior 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.	08.08.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1183_16_elotuzumab_Empliciti/elotuzumab_Empliciti	10.08.2016
Emtricitabine/ Tenofovir Alafenamide Descovy 1169/16	Advice following an abbreviated submission **emtricitabine/tenofovir alafenamide (Descovy®)** is accepted for use within NHS Scotland. Indication under review: in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1. For adult patients in whom emtricitabine/tenofovir is an appropriate combination, Descovy® (emtricitabine/tenofovir alafenamide) offers an alternative to Truvada® (emtricitabine/ tenofovir disoproxil) at no additional cost, and may also be used in patients from 12 years of age.	08.08.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1169_16_emtricitabine_tenofovir_alafenamide_Descovy/emtricitabine_tenofovir_alafenamide_Descovy	10.08.2016

Human alpha - 1 Proteninase Inhibitor Respreeza 1157/16	Advice following a full submission assessed under the orphan equivalent process **Human alpha1-proteinase inhibitor (Respreeza®)** is not recommended for use within NHS Scotland. Indication under review: For maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor (A1-PI) deficiency. Treatment with human A1-PI for two years reduced the rate of lung density loss compared with placebo; however, there is a lack of robust evidence concerning the clinical relevance of this outcome. No improvement in pulmonary exacerbations, lung function or quality of life was demonstrated. The submitting company did not present a sufficiently robust clinical or 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	08.08.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1157_16_human_alpha_1_proteinase_inhibitor_Respreeza/human_alpha_1_proteinase_inhibitor_Respreeza	10.08.2016
Ibrutinib Imbruvica 1150/16	Advice following a full submission assessed under the end of life and ultra-orphan medicine processes **ibrutinib (Imbruvica®)** is accepted for use within NHS Scotland. Indication under review: Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). In a randomised, open-label, phase III study ibrutinib significantly prolonged progression-free survival, the primary endpoint, compared to a chemotherapy treatment, in patients with relapsed or refractory MCL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	08.08.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1150_16_ibrutinib_Imbruvica_MCL/ibrutinib_Imbruvica_MCL	10.08.2016
Ibrutinib Imbruvica 1151/16	Advice following a full submission assessed under the end of life and orphan medicine process **ibrutinib (Imbruvica®)** is accepted for restricted use within NHS Scotland. Indication under review: treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. SMC restriction: patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy. In an open-label, phase III study, ibrutinib significantly increased progression-free survival compared with an anti-CD20 antibody in patients with relapsed or refractory CLL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib. This advice is contingent upon the	08.08.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1151_16_ibrutinib_Imbruvica_CLL/ibrutinib_Imbruvica_CLL	10.08.2016

	continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.			
Insulin Degludec Tresiba 856/13	Advice following a second resubmission **insulin degludec (Tresiba®)** is accepted for use within NHS Scotland. Indication under review: treatment of diabetes mellitus in adults. In three phase III studies in adults with type 1 diabetes mellitus, and five phase III studies in adults with type 2 diabetes mellitus, insulin degludec was non-inferior to other long-acting insulin analogues, assessed by the mean change in glycosylated haemoglobin (HbA1c). Insulin degludec is also indicated for the treatment of diabetes mellitus in adolescents and children from the age of 1 year. The holder of the marketing authorisation has not made a submission to SMC regarding this indication and as a result SMC cannot recommend its use within NHS Scotland.	08.08.2016	Available in line with local guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/856_13_insulin_degludec_Tresiba/insulin_degludec_Tresiba_2nd_Resubmission	10.08.2016
Levofloxacin Quinsair 1162/16	Advice following a full submission under the orphan equivalent process **levofloxacin (Quinsair®)** is accepted for restricted use within NHS Scotland. Indication under review: the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis. SMC restriction: for use as a third line treatment option after colistimethate sodium (first line) and tobramycin (second line). In a phase III open-label randomised study, levofloxacin was non-inferior to another inhaled antimicrobial for change in lung function, measured by relative change in forced expiratory volume in one second (FEV1) percent predicted. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of levofloxacin. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	08.08.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1162_16_levofloxacin_Quinsair/levofloxacin_Quinsair	10.08.2016
Necitumumab Portrazza 1184/16	Advice in the absence of a submission from the holder of the marketing authorisation **necitumumab (Portrazza®)** is not recommended for use within NHS Scotland. Indication under review: in combination with gemcitabine and cisplatin chemotherapy for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer who have not received prior chemotherapy for this condition. 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.	08.08.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1184_16_necitumumab_Portrazza/necitumumab_Portrazza	10.08.2016
Nivolumab	Advice following a resubmission assessed under the end of life and orphan medicine process: **nivolumab (Opdivo®)** is accepted	08.08.2016		10.08.2016

Opdivo 1120/16	for restricted use within NHS Scotland. Indication under review: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. SMC restriction: patients previously untreated with ipilimumab. In a phase III randomised double-blind study, treatment with nivolumab extended overall survival compared with a palliative chemotherapy in patients with previously untreated advanced melanoma without a BRAF mutation. In an ongoing open label phase III study, treatment with nivolumab, at the time of primary analysis, extended overall response rate, compared with investigator's choice of chemotherapy in patients with advanced melanoma previously treated with an anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) treatment or an anti-CTLA-4 treatment and a BRAF inhibitor. The base-case economic analysis submitted by the company assumed that patients were treated for a maximum of two years. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.		Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1120_16_nivolumab_Opdivo/nivolumab_Opdivo_Resubmission	
Rilpivirine Hydrochloride Edurant 1168/16	Advice following an abbreviated submission **rilpivirine (Edurant®)** is accepted for use within NHS Scotland. Indication under review: in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL) ≤ 100,000 HIV-1 RNA copies/mL. The Scottish Medicines Consortium has previously accepted rilpivirine in this indication in adult patients.	08.08.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1168_16_rilpivirine_hydrochloride_Edurant/rilpivirine_hydrochloride_Edurant_	10.08.2016
Secukinumab Cosentyx Psoriatic arthritis 1167/16	Advice following a full submission **secukinumab (Cosentyx®)** is accepted for restricted use within NHS Scotland. Indication under review: alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. SMC restriction: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination. In phase III, randomised, placebo-controlled studies in patients with active psoriatic arthritis, a significantly greater proportion of patients who received secukinumab achieved at least 20% improvement in the American College of Rheumatology response criteria (ACR20) at 24 weeks compared with those who received placebo. This SMC advice	08.08.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1167_16_secukinumab_Cosentyx/secukinumab_Cosentyx	10.08.2016

	takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of secukinumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			

SEPTEMBER 2016				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Bevacizumab Avastin 1190/16	Advice in the absence of a submission from the holder of the marketing authorisation **Bevacizumab (Avastin®)** is not recommended for use within NHS Scotland. Indication under review: In combination with erlotinib for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. 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.	12.09.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1190_16_bevacizumab_Avastin/bevacizumab_Avastin_Non_submision	14.09.2016
Calcipotriol + Betamethasone Enstilar 1182/16	Advice following a abbreviated submission **Calcipotriol and Betamethasone** cutaneous foam (Enstilar®) is accepted for use within NHS Scotland. Indication under review: topical treatment of psoriasis vulgaris in adults. Enstilar® cutaneous foam is another licensed formulation of calcipotriol / betamethasone and may be associated with a small budget impact.	12.09.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1182_16_calcipotriol_betamethasone_Enstilar/calcipotriol_betamethasone_Enstilar_Abbreviated	14.09.2016
Carfilzomib Kyprolis 1171/16	Advice following a full submission assessed under the orphan medicine process **Carfilzomib (Kyprolis®)** is not recommended for use within NHS Scotland. Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Carfilzomib in combination with lenalidomide and dexamethasone improved progression free survival compared with lenalidomide and dexamethasone in adults with relapsed and/or refractory multiple myeloma who had received one to three prior therapies. 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. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	12.09.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1171_16_carfilzomib_Kyprolis/carfilzomib_Kyprolis	14.09.2016
Cobimetinib	Advice in the absence of a submission from the holder of the	12.09.2016	Not available as not recommended for use in	14.09.2016

Cotellic 1191/16	marketing authorisation **Cobimetinib (Cotellic®)** is not recommended for use within NHS Scotland. Indication under review: in combination with vemurafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. 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.		NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1191_16_cobimetinib_Cotellic/cobimetinib_Cotellic_Non_submission	
Dasatinib Sprycel 1170/16	Advice following a full submission assessed under the orphan process **Dasatinib (Sprycel®)** is accepted for use within NHS Scotland. Indication under review: for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase. In an open-label, phase III study, dasatinib was associated with significantly higher cytogenetic and molecular response rates at 12 months compared with another tyrosine kinase inhibitor. There were no differences in progression-free or overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dasatinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	12.09.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1170_16_dasatinib_Sprycel_First_Line/dasatinib_Sprycel_First_Line_Treatment	14.09.2016
Dasatinib Sprycel 371/07	Advice following a re-submission assessed under the orphan process **Dasatinib (Sprycel®)** is accepted for use within NHS Scotland. Indication under review: for the treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate. In patients with chronic, accelerated or blast phase CML, dasatinib produced haematological and cytogenetic responses in two phase III dosing ranging studies. In a phase II study dasatinib was associated with higher haematological and cytogenetic responses relative to another tyrosine kinase inhibitor in patients with chronic phase CML. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dasatinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	12.09.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/dasatinib__20mg__50_mg__70_mg_tablets__Sprycel__ALL/dasatinib__Sprycel__371_07	14.09.2016
Liraglutide Victoza	Advice in the absence of a submission from the holder of the marketing authorisation **Liraglutide (Victoza®)** is not recommended for use within NHS Scotland. Indication under review: As monotherapy for the treatment of	12.09.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advic	14.09.2016

1192/16	adults with type 2 diabetes mellitus to achieve glycaemic control when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance or contraindications. 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.		e/1192_16_liraglutide_Victoza/liraglutide_Victoza_Non_submission	
Idarucizumab Praxbind 1178/16	Advice following a full submission **Idarucizumab (Praxibind®)** is accepted for use within NHS Scotland. Indication under review: idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding. In a phase III, non-randomised, case series study, treatment with idarucizumab reversed the effect of dabigatran, with a median maximum percentage reversal of 100%.	12.09.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1178_16_idarucizumab_Praxbind/idarucizumab_Praxbind	14.09.2016
Iron (III) isomaltoside 1000 Diafer 1177/16	Advice following a full submission **iron (III) isomaltoside 1000 5% (Diafer®)** is not recommended for use within NHS Scotland. Indication under review: For the treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used. Iron (III) isomaltoside 1000 at a higher (10%) concentration has been shown to be non-inferior to another intravenous iron product in maintaining haemoglobin concentration in adult patients with CKD who are iron deficient and are receiving haemodialysis. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	12.09.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1177_16_iron_isomaltoside_1000_Diafer/iron_III_isomaltoside_1000_Diafer	14.09.2016
Paliperidone Trevicta 1181/16	Advice following an abbreviated submission **paliperidone palmitate (Trevicta®)** is accepted for use within NHS Scotland. Indication under review: paliperidone palmitate (Trevicta®), a three-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product. This new formulation of paliperidone palmitate is administered every three months and is available at pro-rata cost to the monthly formulation.	12.09.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1181_16_paliperidone_palmitate_Trevicta/paliperidone_palmitate_3_monthly_Trevicta_Abbreviated	14.09.2016
Trametinib Mekinist 1161/16	Advice following a full submission assessed under the end of life and ultra-orphan medicine process **Trametinib (Mekinist®)** is accepted for restricted use within NHS Scotland. Indication under review: in combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. SMC restriction: to first-	12.09.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1161_16_trametinib_Mekinist/trametinib_0_5mg_and_2mg_Mekinist	14.09.2016

	line treatment. In two phase III studies, trametinib in combination with dabrafenib improved progression-free survival and overall survival compared with BRAF inhibitor monotherapy for the first-line treatment of unresectable or metastatic melanoma with BRAF V600 mutation in adults. This advice takes account of the benefits of Patient Access Schemes (PAS) that improve the cost-effectiveness of trametinib and dabrafenib. This advice is contingent upon the continuing availability of these patient access schemes in NHS Scotland or list prices that are equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.Trametinib is also licensed as monotherapy. As the company submission related only to combination therapy, SMC cannot recommend use as monotherapy.			

OCTOBER 2016				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Aflibercept Eylea 1186/16	Advice following a full submission **Aflibercept 40mg/mL solution for injection (Eylea®)** is accepted for use within NHS Scotland. Indication under review: for adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV). In a phase III, randomised, sham-controlled study in adults with myopic CNV, aflibercept was statistically superior to sham at improving visual acuity at 24 weeks. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	10.10.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1186_16_aflibercept_Eylea/aflibercept_Eylea	12.10.2016
Budesonide Cortiment 1093/15	Advice following a resubmission **Budesonide (Cortiment®)** is accepted for restricted use within NHS Scotland. Indication under review: in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient. SMC restriction: for use in patients with UC who present with active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone, as an alternative to budesonide rectal formulations or off-label oral budesonide. In two phase III studies, budesonide (Cortiment®) significantly increased combined clinical and endoscopic remission at eight weeks compared with placebo. However, there are no comparative data with other oral or rectal	10.10.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1093_15_budesonide_Cortiment/budesonide_Cortiment_Re_Sub	12.10.2016

	preparations.			
Budesonide / Formoterol (Symbicort Turbohaler) 200/6 Inhalation powder and 400/12 Inhalation powder and **Budesonide / Formoterol** (Symbicort) 200 micrograms/6 micrograms per actuation, pressurised inhalation, suspension 1198/16	Advice in the absence of a submission from the holder of the marketing authorisation **budesonide/formoterol inhalation powder (Symbicort Turbohaler®) and pressurised inhalation, suspension (Symbicort®)** are not recommended for use within NHS Scotland. Indication under review: Treatment of patients with chronic obstructive pulmonary disease (COPD) with forced expiratory volume in 1 second (FEV1) 50% to 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this patient group. As a result we cannot recommend its use within NHSScotland. SMC has previously issued accepted advice (97/04) for budesonide/formoterol inhaler (Symbicort Turbohaler) for the symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. This advice may be extended to (Symbicort®) pressurised inhalation, suspension.	10.10.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1198_budesonide_formoterol_Symbicort_Turbohaler/budesonide_formoterol_Symbicort_Non-Sub	12.10.2016
Golimumab Simponi 1199/16	Advice in the absence of a submission from the holder of the marketing authorisation **Golimumab (Simponi®)** is not recommended for use within NHS Scotland. Indication under review: In combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy 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.	10.10.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1199_16_golimumab_Simponi/golimumab_Simponi	12.10.2016
Lenvatinib Lenvima 1179/16	aDVICE following a full submission assessed under the end of life and ultra-orphan medicine processes **lenvatinib (Lenvima®**) is accepted for use within NHS Scotland. Indication under review: treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). Lenvatinib, compared with placebo, significantly improved progression free survival in adults with RAI-refractory DTC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of lenvatinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views	10.10.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1179_lenvatinib_Lenvima/lenvatinib_Lenvima	12.10.2016

	from a Patient and Clinician Engagement (PACE) meeting.			
Nivolumab Opdivo 1180/16	Advice following a full submission assessed under the end of life process **Nivolumab (Opdivo®)** is accepted for restricted use within NHS Scotland. Indication under review: treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. SMC restriction: treatment with nivolumab is subject to a two-year clinical stopping rule. Nivolumab, compared with a standard, second-line chemotherapy, significantly increased overall survival in patients with locally advanced or metastatic non-squamous NSCLC who had received previous therapy including platinum-based doublet chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	10.10.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1180_16_nivolumab_Opdivo/nivolumab_Opdivo_for_non_squamous_NSCLC	12.10.2016
Perampanel Fycompa 1200/16	Advice in the absence of a submission from the holder of the marketing authorisation **Perampanel (Fycompa®)** is not recommended for use within NHS Scotland. Indication under review: Adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised 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.	10.10.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1200_16_perampanel_Fycompa/perampanel_Fycompa_Non_Sub	12.10.2016
Progesterone Lutigest 1185/16	Advice following a full submission **Progesterone (Lutigest®)** is accepted for use within NHS Scotland. Indication under review: Luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women. In women receiving luteal phase support during ART cycles, progesterone (Lutigest®) 100mg vaginal tablets administered three times daily were non-inferior to another progesterone preparation administered vaginally with respect to ongoing pregnancy rates at four to six weeks gestation and live birth rates. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of progesterone 100mg vaginal tablets. This advice is contingent on the continuing availability of the patient access scheme in Scotland or a list price that is equivalent or lower.	10.10.2016	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1185_16_progesterone_Lutigest/progesterone_Lutigest	12.10.2016
Rilpivirine/ Emtricitabine Tenofovir	Advice following an abbreviated submission **Rilpivirine/ Emtricitabine/Tenofovir Alafenamide (Odefsey®)** is accepted for use within NHS Scotland.	10.10.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advic	12.10.2016

Alafenamide Odefsey 1189/16	Indication under review: treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg), infected with human immunodeficiency virus type 1 (HIV 1) without known mutations associated with resistance to the non nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV 1 RNA ≤100,000 copies/mL. For adult patients in whom emtricitabine/rilpivirine/ tenofovir is an appropriate combination, Odefsey® (emtricitabine/ rilpivirine/tenofovir alafenamide) offers an alternative to Eviplera® (emtricitabine/rilpivirine/tenofovir disoproxil) at no additional cost. Odefsey may also be used in patients from the age of 12 years.		e/1189_rilpivirine_emtricitabine_tenofovir_alafenamide_Odefsey/rilpivirine_emtricitabine_tenofovir_alafenamide_Odefsey	
Tocilizumab RoActemra 1201/16	Advice in the absence of a submission from the holder of the marketing authorisation **Tocilizumab (RoActemra®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication / setting. As a result we cannot recommend its use within NHSScotland.	10.10.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1201_16_tocilizumab_RoActemra/tocilizumab_RoActemra_Non_Sub	12.10.2016

NOVEMBER 2016				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Adalimumab Humira® 1208/16	*adalimumab (Humira®) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen; adalimumab (Humira®) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen; adalimumab (Humira®) 40mg/0.8ml vial for paediatric use.* Advice in the absence of a submission from the holder of the marketing authorisation: **adalimumab (Humira®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of moderately active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have 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. SMC	07.11.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1208_16_adalimumab_Humira/adalimumab_Humira_Non-submission	09.11.2016

	has previously accepted adalimumab for restricted use for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies (SMC 880/13). This advice remains valid.			
Adalimumab Humira® 1209/16	*adalimumab (Humira®) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen; adalimumab (Humira®) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen.* Advice in the absence of a submission from the holder of the marketing authorisation: **adalimumab (Humira®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. 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. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of adalimumab 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.	07.11.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1209_16_adalimumab_Humira/adalimumab_Humira_Non_submission	09.11.2016
Canakinumab Ilaris® 1210/16	Advice in the absence of a submission from the holder of the marketing authorisation: **canakinumab (Ilaris®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of active Still's disease including Adult-Onset Still's Disease 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.	07.11.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1210_16_canakinumab_Ilaris/canakinumab_Ilaris_non_submission	09.11.2016
Dequalinium Fluomizin 1194/16	Advice following a full submission: **dequalinium chloride (Fluomizin®)** is accepted for restricted use within NHS Scotland. Indication under review: Treatment of bacterial vaginosis. SMC restriction: In patients for whom the initial treatment is not effective or well tolerated. Non-inferiority of dequalinium vaginal tablets to an antibiotic vaginal cream was demonstrated in a study that	07.11.2016	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1194_16_dequalinium_Fluomizin/dequalinium_Fluomi	09.11.2016

	included treatment-naive and treatment-experienced patients.		zin	
Fampridine Fampyra 789/12	Advice in the absence of a submission from the holder of the marketing authorisation: **fampridine (Fampyra®)** is not recommended for use within NHS Scotland. Indication under review: 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. Advice following a full submission: **fampridine (Fampyra®)** is not recommended for use within NHS Scotland. Indication under review: For the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS [expanded disability status scale] 4 to 7). In two short-term, randomised, double-blind, phase III studies, significantly higher proportions of patients in the fampridine than placebo groups were considered responders, as assessed using the timed 25 foot walk test. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	07.11.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/789_12_fampridine_Fampyra/fampridine_Fampyra	09.11.2016
Lenalidomide Revlimid® 1211/16	*Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules.* Advice in the absence of a submission from the holder of the marketing authorisation: **lenalidomide (Revlimid®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients with relapsed or refractory mantle cell 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 NHSScotland.	07.11.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1211_16_lenalidomide_Revlimid/lenalidomide_Revlimid_non_submission	09.11.2016
Migalastat Galafold 1196/16	Advice following a full submission: **migalastat (Galafold®)** is accepted for restricted use within NHS Scotland. Indication under review: long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation. SMC restriction: in males with classic mutations (leucocyte enzyme activity <1%) treatment should commence at diagnosis; in females and those males with later onset mutations with higher levels of leucocyte enzyme activity, treatment should commence when patients experience uncontrolled pain, evidence of renal, cardiac or neurovascular disease, or gastrointestinal symptoms that significantly reduce quality of life. In an 18-month, randomised, phase III study,	07.11.2016	Available from a specialist centre in another NHS board http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1196_16_migalastat_Galafold/migalastat_Galafold	09.11.2016

	migalastat was comparable to enzyme replacement therapy, measured by mean annualised rate of change in glomerular filtration rate. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of migalastat. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Nivolumab Opdivo 1188/16	Advice following a full submission assessed under the end of life and orphan equivalent process: **nivolumab (Opdivo®)** is not recommended for use within NHS Scotland. Indication under review: as monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults. Nivolumab, compared with an mTOR inhibitor, significantly increased overall survival in patients with advanced or metastatic renal cell carcinoma who had received one or two previous regimens of anti-angiogenic therapy. 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.	07.11.2016	Not available (for this specific indication) as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1188_16_nivolumab_Opdivo_for_renal_cell_carcinoma/nivolumab_Opdivo	09.11.2016
Olaparib Lynparza 1047/15	Advice following a resubmission assessed under the ultra-orphan and end of life process: **olaparib (Lynparza®)** is accepted for use within NHS Scotland. Indication under review: monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy. Olaparib was assessed in a phase II randomised, placebo-controlled study of patients with high grade serous, recurrent, platinum-sensitive ovarian, fallopian-tube or primary peritoneal cancer in which there had been an objective response to the most recent platinum-based chemotherapy regimen. In a pre-planned analysis of the sub-group of patients with BRCA mutation, olaparib was associated with a significantly improved progression-free survival compared with placebo. An interim analysis of overall survival in the BRCA mutation sub-group (70% maturity) demonstrated a benefit of more than four months for olaparib over placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of olaparib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. *Note: Somatic BRCA mutation testing will be available through the*	07.11.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1047_15_olaparib_Lynparza/olaparib_Lynparza_Resubmission	09.11.2016

	genetics consortium.			
Pegaspargase Oncaspar 1197/16	Advice following an abbreviated submission: **pegaspargase (Oncaspar®)** is accepted for use within NHS Scotland. Indication under review: as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients. Pegaspargase (Oncaspar®) has been used in NHS Scotland as an unlicensed medicine for the treatment of ALL in children and adults; it has now been granted a product license.	07.11.2016	Available from a specialist centre in another NHS board http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1197_16_pegaspargase_Oncaspar_/pegaspargase_Oncaspar	09.11.2016
Sofosbuvir/ velpatasvir Epclusa 1195/16	Advice following a full submission: **sofosbuvir-velpatasvir (Epclusa®)** is accepted for restricted use within NHS Scotland. Indication under review: Treatment of chronic hepatitis C virus (HCV) infection in adults. SMC restriction: in patients with genotype 3 (GT3) chronic HCV infection. Sofosbuvir-velpatasvir for 12 weeks, compared with sofosbuvir plus ribavirin for 24 weeks, significantly improved sustained virologic suppression in adults with genotype 3 chronic HCV infection.	07.11.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1195_16_sofosbuvir_velpatasvir_Epclusa/sofosbuvir_velpatasvir_Epclusa	09.11.2016

DECEMBER 2016

Medicine	Condition being treated	Date SMC Advice Published	NHS BORDERS decision	Date NHSB Decision
Cabazitaxel Jevtana 735/11	Advice following a second resubmission assessed under the end of life process **cabazitaxel (Jevtana®)** is accepted for restricted use within NHS Scotland. Indication review: cabazitaxel in combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. SMC restriction: for use in patients who have received at least 225mg/m2 (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. In an open-label, multicentre, randomised-controlled, phase III study in patients with metastatic hormone refractory prostate cancer, treatment with cabazitaxel plus prednisone/prednisolone was associated with an extended median overall survival of 2.4	12.12.2016	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/735_11_cabazitaxel_Jevtana/cabazitaxel_Jevtana_2nd_Resub	14.12.2016

	months compared with an alternative chemotherapy regimen. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cabazitaxel. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting			
Cefuroxime Aprokam 932/13	Advice following an abbreviated submission **cefuroxime (Aprokam®)** is accepted for use within NHS Scotland. Indication under review: antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery. Cefuroxime (Aprokam®) provides a licensed preparation and enables the off-label intracameral use of cefuroxime in cataract surgery to be avoided.	12.12.2016	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/932_13_cefuroxime_sodium_Aprokam/cefuroxime_Aprokam_Abbreviated	14.12.2016
Fentanyl Ionsys 1207/16	Advice in the absence of a submission from the holder of the marketing authorisation **fentanyl transdermal system (Ionsys®)** is not recommended for use within NHS Scotland. Indication under review: Management of acute moderate to severe post-operative pain in adult patients. 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.	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1207_16_fentanyl_Ionsys/fentanyl_Ionsys_Non_Submission	14.12.2016
Ferric maltol Feraccru 1202/16	Advice following a full submission **ferric maltol (Feraccru®)** is not recommended for use within NHS Scotland. Indication under review: in adults for the treatment of iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD). In a pooled analysis of two phase III studies in IBD patients with IDA who had failed previous treatment with oral ferrous products, there was a significantly greater increase in haemoglobin concentrations after 12 weeks of ferric maltol treatment compared with placebo. The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1202_16_ferric_maltol_Feraccru/ferric_maltol_Feraccru	14.12.2016
Hydrocortisone Plenadren 848/12	Advice following a full submission considered under the orphan process **hydrocortisone modified release (Plenadren®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of adrenal insufficiency in adults. Compared with three times daily immediate-release hydrocortisone, once daily modified-release hydrocortisone (taken in the morning) demonstrated approximately 20% lower cortisol exposure over 24 hours. A high cortisol concentration peak in the morning and gradual decline during the afternoon with modified-release hydrocortisone partially reflects the physiological profile. The submitting company did not present a	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/848_12_hydrocortisone_Plenadren/hydrocortisone_Plenadren	14.12.2016

	sufficiently robust clinical and economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			
Idelalisib Zydelig 1212/16	Advice in the absence of a submission from the holder of the marketing authorisation **idelalisib (Zydelig®)** is not recommended for use within NHS Scotland. Indication under review: In combination with ofatumumab for the treatment of adult patients with chronic lymphocytic leukaemia: • who have received at least one prior therapy, or • first line treatment in the presence of 17p deletion or TP53 mutation in patients who are not eligible for any other 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.	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1212_16_idelalisib_Zydelig/idelalisib_Zydelig_Non_Submission	14.12.2016
Ivacaftor Kalydeco 1193/16	Advice following a full submission considered under the ultra-orphan process **ivacaftor (Kalydeco®)** is not recommended for use within NHS Scotland. Indication under review: for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an R117H mutation in the CF transmembrane conductance regulator (CFTR) gene. Ivacaftor, compared to placebo, significantly increased percent predicted forced expiratory volume in one second (ppFEV1) by 5.0% at 24 weeks in a subgroup of patients aged ≥18 years with CF and an R117H mutation of the CFTR gene. 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 sufficiently robust clinical and economic analyses to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1193_16_ivacaftor_Kalydeco/ivacaftor_Kalydeco	14.12.2016
Pembrolizumab Keytruda 1087/15	Advice following a resubmission assessed under the end of life and orphan process **pembrolizumab (Keytruda®)** is not recommended for use within NHS Scotland. Indication under review: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously treated with ipilimumab. In a phase II randomised study, pembrolizumab improved progression free survival compared with chemotherapy in patients with advanced melanoma previously treated with ipilimumab and, if BRAF V600 mutant-positive, a BRAF or MEK inhibitor. 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.	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1087_15_pembrolizumab_Keytruda/pembrolizumab_Keytruda_Resub	14.12.2016

	This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.			
Pertuzumab Perjeta 1121/16	Advice following a re-submission assessed under the orphan process **pertuzumab (Perjeta®)** is not recommended for use within NHS Scotland. Indication under review: For use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence. In a phase II study conducted in women with locally advanced, inflammatory, or early HER2-positive breast cancer, in the neoadjuvant setting, the addition of pertuzumab to trastuzumab plus chemotherapy resulted in a significantly higher proportion of patients achieving pathological complete response in the breast. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	12.12.2016	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1121_16_pertuzumab_Perjeta/pertuzumab_Perjeta	14.12.2016

JANUARY 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Buprenorphine Transdermal patch Butec 1213/17	Advice following a full submission, **Buprenorphine Transdermal patches (Butec®)** are accepted for restricted use within NHS Scotland. Indication under review: In adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. SMC restriction: for use in elderly patients (over 65 years). Non-inferiority was demonstrated between buprenorphine weekly patches and twice daily oral tramadol in patients with moderate to severe osteoarthritic pain. Non-inferiority was also demonstrated between buprenorphine weekly patches plus oral paracetamol and co-codamol in patients with severe osteoarthritic pain.	16.01.2017	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1213_17_buprenorphine_transdermal_patch_Butec/buprenorphine_transdermal_patch_Butec	08.02.2017

Carfilzomib Kyprolis 1171/16	Advice following a resubmission assessed under the orphan medicine process, **Carfilzomib (Kyprolis®)** is not recommended for use within NHS Scotland. Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Carfilzomib in combination with lenalidomide and dexamethasone improved progression free survival compared with lenalidomide and dexamethasone in adults with relapsed and / or refractory multiple myeloma who had received one to three prior therapies. 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. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	16.01.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1171_16_carfilzomib_Kyprolis/carfilzomib_Kyprolis_Resub	08.02.2017
Dalbavancin Xydalba 1105/15	Advice following a full submission, **Dalbavancin (Xydalba®)** is accepted for restricted use within NHS Scotland. Indication under review: treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. SMC restriction:for second-line use or when meticillin-resistant Staphylococcus aureus (MRSA) infection is suspected, or on the advice of local microbiologists or specialists in infectious disease, and the patient is initially hospitalised due to ABSSSI, requires intravenous antibiotics, but is eligible for early discharge as soon as their medical condition does not require further inpatient treatment. In two phase III double-blind studies of patients with ABSSSI, dalbavancin was non-inferior to the comparator for clinical response at end of treatment in the clinically evaluable population.	16.01.2017	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1105_15_dalbavancin_Xydalba/dalbavancin_Xydalba	08.02.2017
Daratumumab Darzalex 1205/17	Advice following a full submission considered under the end of life and orphan process, **Daratumumab (Darzalex®)**: is not recommended for use within NHS Scotland. Indication under review: as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. In a pooled analysis of patients in a phase I/II and a phase II study, with heavily pre-treated multiple myeloma, who received the licensed dosing schedule of daratumumab, there was an overall response rate of 31%. The submitting company's justification of the treatment's costs in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic and	16.01.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1205_17_daratumumab_Darzalex/daratumumab_Darzalex	08.02.2017

	clinical analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			
Deferasirox Exjade 347/07	Advice following a resubmission considered under the ultra-orphan process, **Deferasirox (Exjade®)** is accepted for restricted use within NHS Scotland. Indication under review: Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias. The current advice relates only to use in the myelodysplastic syndrome (MDS) population. SMC restriction: use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate -1 risk. Plasma ferritin levels were statistically significantly reduced from baseline to end of study in two phase II/III open-label, single-arm studies of patients with MDS with an IPSS score of low or intermediate -1 risk. SMC has previously accepted deferasirox for restricted use for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions. This advice remains valid. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	16.01.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/347_07_deferasirox_Exjade/deferasirox_Exjade_Resub	08.02.2017
Elbasvir-Grazoprevir Zepatier 1203/17	Advice following a full submission, **Elbasvir-grazoprevir (Zepatier®)** is accepted for use within NHS Scotland. Indication under review: Treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes). In patients with genotype 1a, 1b or 4, elbasvir-grazoprevir significantly increased sustained virologic suppression compared with a regimen containing a non-structural protein 5B (NS5B) inhibitor, an interferon and ribavirin. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of elbasvir-grazoprevir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	16.01.2017	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1203_17_elbasvir-grazoprevir_Zepatier/elbasvir-grazoprevir_Zepatier	08.02.2017
Eltrombopag Revolade 1206/17	Advice following an abbreviated submission, **Eltrombopag (Revolade®)** is accepted for restricted use within NHS Scotland. Indication under review: chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to 17 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). SMC restriction: use in patients with severe symptomatic ITP or a high risk of bleeding. Eltrombopag has	16.01.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1206_17_eltrombopag_Revolade/eltrombopag_Revolade_Abbreviated	08.02.2017

	previously been accepted for restricted use in adult patients with chronic immune (idiopathic) thrombocytopenic purpura. The license has been extended to include children from 1 year. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eltrombopag. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Oestrogens, conjugated, bazedoxifene acetate Duavive 1220/17	Advice in the absence of a submission from the company, **Oestrogens, conjugated, bazedoxifene acetate (Duavive®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. The company has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	16.01.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1220_17_oestrogens_conjugated_Duavive/oestrogens_conjugated_Duavive_Non_Sub	08.02.2017
Pembrolizumab Keytruda 1204/17	Advice following a full submission assessed under the end of life and orphan medicine process, **Pembrolizumab (Keytruda®)** is accepted for restricted use within NHS Scotland. Indication under review: The treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) and who have received at least one prior chemotherapy regimen. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. Pembrolizumab, compared with a standard taxane monotherapy, significantly improved overall survival in adults with advanced NSCLC tumours that express PD-L1 and have progressed after platinum-doublet chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	16.01.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1204_17_pembrolizumab_Keytruda/pembrolizumab_Keytruda	08.02.2017

FEBRUARY 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Botulinum Toxin	Advice following a resubmission, **Botulinum Toxin A (Botox®)**	13.02.2017	Not routinely available as local clinical	08.03.2017

Type A BOTOX® 692/11	is accepted for restricted use within NHS Scotland. Indication under review: 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). SMC restriction: use in adults with chronic migraine whose condition has failed to respond to ≥3 prior oral prophylactic treatments, where medication overuse has been appropriately managed. In pooled analysis of the two pivotal phase III studies, botulinum toxin type A (Botox®) significantly reduced the frequency of headache days compared with placebo.		experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/692_11_botulinum_toxin_type_a_BOTOX/botulinum_toxin_type_a_Botox_Resubmission	
Desmopressin Oral Lyophilisate Noqdirna® 1218/17	Advice following a full submission, **Desmopressin (Noqdirna®)** is not recommended for use within NHS Scotland. Indication under review: Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. Two phase III, placebo-controlled studies demonstrated that desmopressin, at licensed doses over three months, significantly reduced the mean number of nocturnal voids and resulted in higher proportions of responders compared with placebo, in patients with nocturia. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	13.02.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1218_17_desmopressin_Noqdirna/desmopressin_Noqdirna	08.03.2017
Everolimus Afinitor® 1215/17	Advice following a full submission assessed under the ultra-orphan medicine process, **Everolimus (Afinitor®)** is accepted for use within NHS Scotland. Indication under review: for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease. Treatment with everolimus improved progression-free survival, when compared with placebo, in patients with progressive, advanced, well-differentiated, non-functioning neuroendocrine tumours of gastrointestinal or lung origin. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	13.02.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1215_17_everolimus_Afinitor/everolimus_Afinitor_NETs	08.03.2017
Evolocumab Repatha® 1148/16	Advice following a resubmission, **Evolocumab (Repatha®)** is accepted for restricted use within NHS Scotland. Indication under review: in adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid	13.02.2017	Available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1148_16_evolocumab_Repatha/evolocumab_Repatha_Resub	08.03.2017

	lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or, • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. • SMC restriction: for specialist use only, when administered at a dose of 140mg every two weeks, in patients at high cardiovascular risk as follows: • patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L for primary prevention of cardiovascular events or, • patients with HeFH and LDL-C ≥3.5mmol/L for secondary prevention of cardiovascular events or, • patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L or • patients with recurrent/polyvascular disease and LDL-C ≥3.5mmol/L In phase III clinical studies, treatment with evolocumab added to optimised background lipid-lowering therapy significantly improved mean percentage change in LDL-C from baseline to week 12, versus placebo and another lipid-lowering treatment, in patients with heterozygous familial and non-familial hypercholesterolaemia and mixed dyslipidaemia. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of evolocumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. SMC cannot recommend the use of evolocumab in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies as the company's submission related only to its use in primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) and mixed dyslipidaemia.			
Iron (III) isomaltoside 1000 Diafer® 1177/16	Advice following a resubmission, **Iron III isomaltoside 1000 5% (Diafer®)** is accepted for use within NHS Scotland. Indication under review: For the treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used. Iron III isomaltoside 1000 at a higher (10%) concentration has been shown to be non-inferior to another intravenous iron product in maintaining haemoglobin concentration in adult patients with	13.02.2017	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1177_16_iron_isomaltoside_1000_Diafer/iron_III_isomaltoside_1000_Diafer_Resub	08.03.2017

	CKD who are iron deficient and are receiving haemodialysis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of iron III isomaltoside 1000 5%. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
Osimertinib Tagrisso® 1214/17	Advicefollowing a full submission assessed under the ultra orphan and end of life process, **Osimertinib (Tagrisso®)** is accepted for restricted use within NHS Scotland. Indication under review: the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC). SMC Restriction: in patients who have received previous treatment with an EGFR tyrosine kinase inhibitor. Osimertinib was associated with an overall response rate of 66% in the pooled analysis of two phase II single-arm studies of patients with EGFR T790M advanced NSCLC who had received previous treatment with an EGFR tyrosine kinase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of osimertinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. Please note, circulating tumour DNA (ctDNA) plasma testing for EGFR T790M mutation status will be available via the Molecular Pathology Laboratory Consortium. Requests should be directed to the regional lab in Aberdeen, Dundee, Edinburgh or Glasgow.	13.02.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1214_17_osimertinib_Tagrisso/osimertinib_Tagrisso	08.03.2017
Pitolisant Wakix® 1229/17	Advice in the absence of a submission from the holder of the marketing authorisation, **Pitolisant (Wakix®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of narcolepsy with or without cataplexy 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.	13.02.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1229_17_pitolisant_Wakix/pitolisant_Wakix	08.03.2017
Trifluridine, Tipiracil Lonsurf® 1221/17	Advice following a full submission assessed under the end-of-life and orphan-equivalent process, **Trifluridine/Tipiracil (Lonsurf®)** is accepted for use within NHS Scotland. Indication under review: The treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti vascular endothelial growth factor	13.02.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1221_17_trifluridine_tipiracil_as_hydrochloride_Lonsurf/trifluridine_tipiracil_as_hydrochloride_Lonsurf	08.03.2017

	agents, and anti-epidermal growth factor receptor agents. Treatment with trifluridine/tipiracil was associated with an improvement in overall survival when compared with best supportive care in patients who had received, or were intolerant of, first and second-line therapies for metastatic CRC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of trifluridine/tipiracil. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.			
Vernakalant Brinavess® 1222/17	Advice in the absence of a submission from the holder of the marketing authorisation, **Vernakalant (Brinavess®)** is not recommended for use within NHS Scotland. Indication under review: Rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults • For non-surgery patients: atrial fibrillation ≤ 7 days duration • For post-cardiac surgery patients: atrial fibrillation ≤ 3 days duration 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.	13.02.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1222_17_vernakalant_Brinavess/vernakalant_Brinavess	08.03.2017

MARCH 2017				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Abatacept Orencia® 1230/17	Advice in the absence of a submission from the holder of the marketing authorisation, **Abatacept (Orencia®),**125mg solution for injection (pre-filled syringe) 125mg solution for injection in pre-filled pen 250mg powder for concentrate for solution for infusion, is not recommended for use within NHS Scotland. Treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate. 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.	13.03.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1230_17_abatacept_Orencia/abatacept_Orencia	08.03.2017
Lacosamide Vimpat®	Advice in the absence of a submission from the holder of the marketing authorisation, **Lacosamide (Vimpat)**, 50mg / 100mg / 150mg / 200mg film-coated tablets / 10mg/mL solution for infusion / 10mg/mL syrup UCB, is not recommended for use within NHS Scotland.	13.03.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1231_17_lacosamide_Vimpat/lacosamide_Vimpat	08.03.2017

1231/17	Indication under review: As monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with 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.			
Liposomal irinotecan Onivyde 1217/17	Advice following a full submission assessed under the orphan and end of life process, **Liposomal irinotecan (Onivyde®)** is not recommended for use within NHS Scotland. Indication under review: Treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil (5-FU) and leucovorin (folinic acid), in adult patients who have progressed following gemcitabine based therapy. The addition of liposomal irinotecan to 5-FU/folinic acid, compared with 5-FU/folinic acid alone, significantly improved overall survival and progression free survival in patients with metastatic adenocarcinoma of the pancreas who had progressed after gemcitabine based therapy.The submitting company's justification of the treatment's costs in relation to its health benefits was not sufficient and in addition did not present a sufficiently robust clinical or economic case to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	13.03.2017	Not available as not recommended for use in NHSScotland http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1217_19_liposomal_irinotecan_Onivyde/liposomal_irinotecan_Onivyde	08.03.2017
Obinutuzumab Gazyvaro 1219/17	Advice following a full submission considered under the ultra-orphan-medicine process, **Obinutuzumab (Gazyvaro®)** is accepted for use within NHS Scotland. Indication under review: obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen. Obinutuzumab plus bendamustine induction therapy followed by obinutuzumab maintenance significantly increased progression free survival compared with bendamustine monotherapy induction without any maintenance treatment, in patients with rituximab-refractory follicular lymphoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of obinutuzumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	13.03.2017	Routinely available in line with national guidance http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1219_17_obinutuzumab_Gazyvaro/obinutuzumab_Gazyvaro	08.03.2017