Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2014 – 31st March 2015

April – May 2014

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – April – May 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
aflibercept intravitreal (Eylea®)	954/14	For adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.	07.04.2014	09.04.2014	**Included** in NHS Borders formulary for the SMC approved indication.
aripiprazole (Abilify)	962/14	Maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole.	12.05.2014		**Included** in NHS Borders formulary for the SMC approved indication.
azithromycin (Zedbac)	950/14	The treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required.	07.04.2014	09.04.2014	**Not Included in** NHS Borders formulary because NHS Borders decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question.
certolizumab pegol (Cimzia)	960/14	For the treatment of adult patients with severe active axial spondyloarthritis.	12.05.2014	11.06.2014	**Included** in NHS Borders formulary for the SMC approved indication
dimethyl fumarate (Tecfidera)	886/13	Treatment of adult patients with relapsing remitting multiple sclerosis.	07.04.2014	09.04.2014	**Included** in NHS Borders formulary for the SMC approved indication.
dolutegravir (Tivicay)	961/14	In combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age	12.05.2014	11.06.2014	**Included** in NHS Borders formulary for the SMC approved indication
rilpivirine 25mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®)	951/14	Treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load ≤100,000 HIV-1 RNA copies/mL. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®.	07.04.2014	09.04.2014	**Included** in NHS Borders formulary for the SMC approved indication.
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – April – May 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**

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adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®)	682/11	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present.	07.04.2014	09.04.2014	**Included** in NHS Borders formulary for the SMC approved indication
fluticasone furoate/vilanterol (Relvar Ellipta)	953/14	Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	07.04.2014	11.06.2014	**Included** in NHS Borders formulary for the SMC approved indication
lenalidomide (Revlimid)	441/08	In combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy).	07.04.2014	09.04.2014	**Prescribing would be under SCAN regime**
lipegfilgrastim, 6mg, solution for injection (Lonquex®)	908/13	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).	07.04.2014	09.04.2014	**Prescribing would be under SCAN regime**
macitentan (Opsumit)	952/14	As monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension in adult patients of World Health Organisation Functional Class II to III.	07.04.2014	09.04.2014	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – April – May 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
cobicistat (Tybost)	933/13	Pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults.	12.05.2014		**Not SMC approved** – not approved for use in NHS Borders
infliximab (Remicade)	374/07	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.	12.05.2014		**Not SMC approved** – not approved for use in NHS Borders

Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2014 – 31st March 2015

June – July 2014

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – June – July 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
budesonide gastro-resistant granules (Budenofalk®)	970/14	Induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon.	09.06.2014	11.06.2014	**Non – formulary** – NHS Borders specialists do not support formulary inclusion
defibrotide (Defitelio®)	967/14	Treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy.	09.06.2014	09.05.2014	Product would not be used in NHS Borders
fluticasone furoate / vilanterol (Relvar Ellipta®)	966/14	For the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists.	09.06.2014	09.05.2014	**Included** in NHS Borders formulary for the SMC approved indication
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – June – July 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
sofosbuvir 400mg tablet (Sovaldi®)	964/14	In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.	09.06.2014	09.05.2014	**Included** in NHS Borders formulary for the SMC approved indication
canagliflozin (Invokana®)	963/14	In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.	09.06.2014	09.05.2014	**Non – formulary** – NHS Borders specialists do not support formulary inclusion
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – June – July 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**

avanafil (Spedra®)	980/14	For the treatment of erectile dysfunction in adult men.	09.06.2014	09.05.2014	**Not SMC approved** – not approved for use in NHS Borders
natalizumab (Tysabri®)	979/14	Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate.	09.06.2014	09.05.2014	**Not SMC approved** – not approved for use in NHS Borders for this indication. Advice has been superseded
paclitaxel albumin (Abraxane®)	968/14	In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	09.06.2014	09.05.2014	**Not SMC approved** – not approved for use in NHS Borders

August – September 2014

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – August – September 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – August – September 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
ocriplasmin (Jetrea®) Thrombogenics	892/13	In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns.	11.08.2014	20.08.2014	Product would not be used in NHS Borders
tocilizumab (RoActemra®) Roche	982/14	In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.	11.08.2014	20.08.2014	**Included** in NHS Borders formulary for the SMC approved indication
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – August – September 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**

colestilan (BindRen®) Mitsubishi Pharma	939/14	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	11.08.2014	20.08.2014	**Not recommended for use in NHS Borders - not recommended by SMC**
lubiprostone (Amitiza®) Sucampo	977/14	For the treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures (e.g. educational measures, physical activity) are inappropriate.	11.08.2014	20.08.2014	**Not recommended for use in NHS Borders - not recommended by SMC**
racecadotril (Hidrasec®) Abbott Healthcare Products Ltd.	818/12	Complementary symptomatic treatment of acute diarrhoea in infants (older than three months), and in children, together with oral rehydration, and the usual support measures, when these measures alone are insufficient to control the clinical condition and when causal treatment is not possible.	11.08.2014	20.08.2014	**Not recommended for use in NHS Borders - not recommended by SMC**
umeclidinium bromide / vilanterol (Anoro®) GSK	978/14	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	11.08.2014	20.08.2014	**Not recommended for use in NHS Borders - not recommended by SMC. Advice has been superseded**

October – November 2014

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – October – November 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
dabigatran etexilate (Pradaxa®) Boehringer Ingelhiem	995/14	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Dabigatran etexilate was non-inferior to a vitamin K antagonist for recurrent symptomatic venous thromboembolism events (VTE) and death related to VTE in three phase III studies (two in the treatment of DVT/PE and one in the prevention of recurrent DVT/PE). The economic case was based on evidence relating to a maximum of 18 months treatment so the cost-effectiveness of longer term use is uncertain.	13.10.2014	10.12.2014	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;
misoprostol (Mysodelle®) Ferring Pharmaceuticals	996/14	Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated. Misoprostol vaginal delivery system significantly reduced the time to vaginal delivery, with a	13.10.2014	10.12.2014	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;

		similar rate of caesarean section, compared with an active comparator.			
azelastine hydrochloride + fluticasone propionate (Dymista®) Meda Pharma	921/13	For the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient. For patients in whom the combination of azelastine hydrochloride and fluticasone propionate nasal spray is an appropriate choice of therapy, Dymista® provides the two ingredients in a single nasal spray. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Dymista®. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	13.10.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
ipilimumab (Yervoy®) Bristol Myers Squibb NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	997/14	Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use). In a phase III, randomised study median overall survival was extended by 2.1 months in patients treated with ipilimumab plus dacarbazine (an unlicensed dose regimen) compared with dacarbazine alone. Efficacy data for the licensed dose of ipilimumab are limited to two retrospective single-arm observational studies where median overall survival was 11.5 to 14.3 months. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Ipilimumab. 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.	10.11.2014	10.12.2014	**Prescribing would be under SCAN regime**
saxagliptin (Onglyza) AstraZeneca	772/12	In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. A phase IIIb, randomised, double-blind, placebo-controlled, parallel-group study in adult patients with type 2 diabetes mellitus and inadequate glycaemic control on a stable dose of insulin showed that addition of saxagliptin 5mg daily was superior to placebo for the primary endpoint of change from baseline in HbA1c at 24 weeks. The manufacturer's submission related only to the use of saxagliptin in combination with insulin (with or without metformin). SMC cannot recommend the use of	10.11.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication

		saxagliptin as monotherapy.			
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – October – November 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
empagliflozin (Jardiance®) Boehringer-Ingelheim / Eli Lilly	993/14	Treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy: in combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: to use in the following situations: • dual therapy in combination with metformin, when a sulphonylurea is inappropriate • triple therapy in combination with metformin plus standard of care • add-on to insulin therapy in combination with insulin plus standard of care Empagliflozin was superior to placebo for glycaemic control in combination with various anti-diabetic medicines (metformin; metformin plus sulphonylurea; thiazolidinedione ± metformin; and insulin) and it was non-inferior to a sulphonylurea in combination with metformin. Empagliflozin is also indicated as monotherapy in patients who cannot tolerate metformin. SMC cannot recommend the use of empagliflozin as monotherapy as the company's submission did not include evidence of cost-effectiveness in this setting.	13.10.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
lurasidone (Latud[a®]) Sunovion	994/14	For the treatment of schizophrenia in adults aged 18 years and over. SMC Restriction: as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects. Lurasidone demonstrated benefit over placebo in mean change from baseline in Positive and Negative Syndrome Scale (PANSS) total score after six weeks of treatment and was non-inferior to another second generation antipsychotic medicine for time to relapse over 12 months.	13.10.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
brentuximab vedotin (Adcetris) Takeda	989/14	Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or	13.10.2014	10.12.2014	**Prescribing would be under SCAN regime**

		multi-agent chemotherapy is not a treatment option and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). SMC restriction: treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option In an open-label, single-arm study, patients with relapsed or refractory Hodgkin lymphoma treated with brentuximab vedotin achieved an objective response rate of 75%. Controlled data with clinical outcomes are currently lacking. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. Brentuximab is also indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). SMC cannot recommend use in sALCL as the company did did not include evidence for use in this indication in its submission.			
capsaicin (Qutenza®) Astellas Pharma Ltd	673/11	For the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. SMC restriction: to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments. A phase IV, open-label, randomised, controlled study showed that capsaicin patch was non-inferior to an oral analgesic in adult patients with peripheral neuropathic pain.	13.10.2014	10.12.2014	Extension of licence for product currently approved for use in NHS Borders
alogliptin plus metformin (Vipdomet®) Takeda UK Ltd	998/14	In the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus: • as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin. • in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone. • in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and	13.10.2014	10.12.2014	**Not Included** in NHS Borders formulary because NHS Borders decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question;

		exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. SMC restriction: to use in patients for whom this fixed dose combination of alogliptin and metformin is an appropriate choice of therapy and only when the addition of a sulphonylurea to metformin monotherapy is not appropriate. For patients in whom dual combination therapy with metformin and aloglitpin is appropriate it has the potential to reduce the pill burden at no additional cost. Alogliptin/metformin is licensed for use in triple combination therapy with pioglitazone or as add-on to insulin. The manufacturer's submission related only to the use of alogliptin/ metformin in dual therapy, therefore SMC cannot recommend the use of alogliptin/ metformin in triple therapy with either pioglitazone or insulin.			
posaconazole (Noxafil®) Merck Sharp & Dohme Ltd	999/14	In the treatment of the following fungal infections in adults: Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; • Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; • Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; • Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. For prophylaxis of invasive fungal infections in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; • Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus	13.10.2014	10.12.2014	**Approved for use in NHS Borders** for prophylaxis of invasive fungal infections in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; • Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections. As per SMC restriction.

		host disease and who are at high risk of developing invasive fungal infections. SMC restriction: to patients in whom there is a specific risk of Aspergillus infection or where fluconazole or itraconazole are not tolerated on the advice of local microbiologists or specialists in infectious diseases. Posaconazole plasma concentrations are generally higher following administration of posaconazole tablets than posaconazole oral suspension. The tablet and oral suspension are therefore not to be used interchangeably. While the tablets are cost saving when administered for treatment they are significantly more expensive than the oral suspension when administered for prophylaxis.			
daclatasvir (Daklinza) BMS	1002/14	In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults. SMC restriction: use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis. In a phase II study 89% to 99% of patients with genotype 1 and 3 HCV treated with daclatasvir in various peginterferon-free regimens achieved a sustained virological response at 12 weeks (SVR12). In a phase III study of patients with genotype 4 HCV, the superiority of daclatasvir with peginterferon-alfa plus ribavirin (PR) versus placebo + PR was demonstrated for the primary endpoint of SVR12.	10.11.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
aflibercept (Eylea) Bayer	1003/14	For adults for the treatment of visual impairment due to diabetic macular oedema (DMO). SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline. Intravitreal aflibercept significantly improved BCVA at 52 weeks compared with laser photocoagulation in two phase III, double-masked studies. 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, or a list price that is equivalent or lower, in NHS Scotland.	10.11.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – October – November 2014					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**

			Published		
trastuzumab emtansine (Kadcyla) Roche NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	990/14	As a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy. In a randomised phase III open-label study, trastuzumab emtansine (Kadcyla®) conferred a median six months additional survival benefit compared with an active comparator. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	13.10.2014	10.12.2014	**Not recommended for use in NHS Borders - not recommended by SMC**
denosumab (Prolia®) 60 mg solution for injection in a pre-filled syringe. Amgen Ltd	1013/14	Osteoporosis in men at increased risk of fractures. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of denosumab 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.	10.11.2014	10.12.2104	**Not recommended for use in NHS Borders - not recommended by SMC**
voriconazole (Vfend®) 50 mg and 200 mg film-coated tablets / 200 mg powder for solution for infusion / 200 mg powder and solvent for solution for infusion / 40 mg/ml powder for oral suspension. Pfizer Ltd	1014/14	Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients. The holder of the 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.	10.11.2014	10.12.2014	**Not recommended for use in NHS Borders - not recommended by SMC**
telavancin hydrochloride (Vibativ®) 250 mg and 750 mg powder for concentrate for solution for infusion. Clinigen Healthcare Ltd	1015/14	Treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA). The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use	10.11.2014	10.12.2014	**Not recommended for use in NHS Borders - not recommended by SMC**

		within NHSScotland.			

December 2014 – January 2015

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – December 2014 – January 2015					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
obinutuzumab (Gazyvaro) Roche	1008/14	In combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy. The combination of obinutuzumab plus chlorambucil produced a statistically and clinically significant increase in progression free survival compared with an alkylating agent alone or an alkylating agent/antibody combination, in older patients with previously untreated CLL who had substantial comorbidities.	08.12.2014	10.12.2014	**Prescribing would be under SCAN regime**
umeclidinium (Incruse) GSK	1004/14	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Two randomised controlled, phase III studies demonstrated that after 12 and 24 weeks of treatment umeclidinium improved lung function compared with placebo in patients with moderate to severe COPD. There was also improvement in symptomatic outcomes such as dyspnoea. Umeclidinium is an alternative to other long-acting muscarinic antagonists (LAMAs).	08.12.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
pemetrexed (Alimta) Lilly UK NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	770/12	Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. In patients with locally advanced or metastatic non-squamous non-small cell lung cancer, maintenance treatment with pemetrexed, following completion of first-line platinum-based chemotherapy, was associated with prolonged overall survival and progression-free survival when compared with placebo.	08.12.2014	10.12.2014	**Prescribing would be under SCAN regime**

Pomalidomide (IMNOVID) Celgene	972/14	In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Pomalidomide plus dexamethasone significantly increased progression-free survival compared with high-dose dexamethasone in patients with refractory or relapsed and refractory multiple myeloma. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pomalidomide. 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.	08.12.2014	10.12.2014	**Prescribing would be under SCAN regime**
50mg dolutegravir (as sodium), 600mg of abacavir (as sulfate), and 300mg of lamivudine (Trimeq) ViiV UK/GSK	1009/14	For the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg. In patients for whom this combination is appropriate, it offers a single tablet at a lower cost per dose compared with the individual components. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of (Triumeq®). 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.	08.12.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
10mg (1%) clindamycin (as clindamycin phosphate and 0.25mg (0.025%) tretinion (Treclin) Media Pharmaceuticals	1010/14	For the topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older. For use in patients for whom a topical combination of clindamycin and tretinoin is an appropriate choice of therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of clindamycin 1% / tretinoin 0.025% gel. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	08.12.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication
Cholecalciferol 0.625mg equivalent to 25,000IU of vitamin D (InvitaD3) Consilient Health (UK) Ltd	1011/14	The prevention and treatment of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. The therapeutic use and safety profile of cholecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. InVita D3® provides a higher strength preparation than	08.12.2014	10.12.2014	**Included** in NHS Borders formulary for the SMC approved indication

		some other licensed vitamin D preparations and is licensed for use in both children and adults. At equivalent doses, it is a similar cost to other vitamin D preparations. InVitaD3® is listed in the British National Formulary for Children 2014-2015.			
peginterferon beta-1a (Plegridy) Biogen Idec	1018/14	In adult patients for the treatment of relapsing remitting multiple sclerosis. Peginterferon-beta-1a, compared with placebo, improved annualised relapse rate in adults with relapsing remitting multiple sclerosis.	12.01.2015	11.02.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion
olodaterol respimat soft mist inhaler (Striverdi Respimat) Boehringer-Ingelheim	974/14	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease. In two 48-week studies there was no significant difference between olodaterol 5 microgram and another long acting beta2 agonist for the primary endpoints of trough forced expiratory volume in 1 second (FEV1) and FEV1 area under curve (0 to 3 hours) at week 24.	12.01.2015	11.02.2015	**Not Included** in NHS Borders formulary because NHS Borders decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – December 2014 – January 2015					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
riociguat (Adempas) Bayer NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1001/14	Chronic thromboembolic pulmonary hypertension (CTEPH): Treatment of adult patients with World Health Organisation (WHO) functional class II to III with • inoperable CTEPH, • persistent or recurrent CTEPH after surgical treatment, to improve exercise capacity. SMC restriction: for patients in whom a PDE5 inhibitor is inappropriate, not tolerated, or ineffective. Riociguat demonstrated significant improvement compared with placebo in exercise capacity, in terms of 6-minute walk distance, in patients with inoperable CTEPH or persistent or recurrent pulmonary hypertension after pulmonary endarterectomy. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of riociguat. 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. Riociguat is also indicated for use in pulmonary arterial hypertension. The company submitted clinical and cost-effectiveness evidence for its use in CTEPH only.	08.12.2014	10.12.2014	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit

brimonidine (Mirvaso) Galderma	1016/14	The symptomatic treatment of facial erythema of rosacea in adult patients. SMC restriction: for use in patients with moderate to severe persistent facial erythema associated with rosacea. Two identical phase III studies demonstrated that brimonidine 0.33% gel significantly reduced erythema compared with vehicle gel in patients with rosacea.	12.01.2015	11.02.2015	**Included** in NHS Borders formulary for the SMC approved indication
omalizumab (Xolair) Novartis	1017/14	As add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment. SMC restriction: use in adults and adolescents with chronic spontaneous urticaria who have an inadequate response to combination therapy with H1 antihistamines, leukotriene receptor antagonists (LTRA) and H2 antihistamines, used according to current treatment guidelines. The addition of omalizumab to combination therapy with H1-antihistamines, and/or leukotriene receptor antagonists and/or H2-antihistamines was more effective than placebo in reducing the weekly itch severity score (ISS) at 12 weeks. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of omalizumab. 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.	12.01.2015	11.02.2015	**Included** in NHS Borders formulary for the SMC approved indication
cetuximab (Erbitux®) Merck Serono NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1012/14	Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer: • in combination with irinotecan-based chemotherapy • in first-line in combination with FOLFOX; • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. SMC restriction: for use in patients with RAS wild-type metastatic colorectal cancer, in combination with irinotecan or oxaliplatin-based chemotherapy, in patients who have not previously received chemotherapy for their metastatic disease (first-line treatment). Efficacy data for the RAS wild-type population come from post hoc subgroup analyses of two studies that compared cetuximab plus chemotherapy with	12.01.2015	11.02.2015	**Prescribing would be under SCAN regime**

		chemotherapy alone. In the RAS wild-type population, response rates (complete and partial responses) were significantly higher in both studies and overall survival was significantly longer in one study for cetuximab plus chemotherapy than chemotherapy alone. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cetuximab. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.			
aztreonam lysine (Cayston) Gilead Sciences NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	753/12	Suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis aged six years and older. SMC restriction: When inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit (measured as ≥2% decline in forced expiratory volume in 1 second [FEV1]). Aztreonam lysine has demonstrated superiority in improving lung function and respiratory symptoms in one active-controlled study and two 28-day placebo-controlled studies in patients with cystic fibrosis and chronic Pseudomonas aeruginosa infection. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of aztreonam lysine. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	12.01.2015	11.02.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion
canagliflozin/metformin (Vokanamet) Janssen-Cilag Ltd	1019/14	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: • in patients not adequately controlled on their maximally tolerated doses of metformin alone; • in patients on their maximally tolerated doses of metformin along with other glucose-lowering medicinal products, including insulin, when these do not provide adequate glycaemic control; • in patients already being treated with the combination of canagliflozin and metformin as separate tablets. SMC restriction: use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy Canagliflozin in combination with metformin has been shown to be bioequivalent to canagliflozin and	12.01.2015	11.02.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion

		metformin administered separately and canagliflozin administered twice daily has been shown to provide similar exposure to the equivalent dose administered once daily.			
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – December 2014 – January 2015					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
Tocilizumab (RoActemra) Roche	1020/14	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. As a result we cannot recommend its use within NHSScotland.	08.12.2014	10.12.2014	**Not recommended for use in NHS Borders - not recommended by SMC**
bevacizumab (Avastin) Roche NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	806/12	In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Addition of bevacizumab to standard chemotherapy with carboplatin and paclitaxel increased progression-free survival and, in women with stage III and residual disease after surgical debulking or stage IV disease, it increased overall survival. 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.	12.01.2015	11.02.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

February 2015 – March 2015

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland –February 2015 – March 2015					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
follitropin alfa (Bemfola®) FINOX Biotech	1025/15	In adult women for: • anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene	09.02.2015	11.02.2015	**Product would not be used in NHS Borders**

		citrate. • stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer. • in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and follicle-stimulating hormone (FSH) deficiency. In clinical trials these patients were defined by an endogenous serum LH level <1.2 units/L. • In adult men for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human chorionic gonadotrophin (hCG) therapy. Follitropin alfa (Bemfola®) is a biosimilar that has demonstrated clinical equivalence to another follitropin alfa product for stimulation of multi-follicular development for superovulation in ART. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.			
umeclidinium / vilanterol (Anoro®) GSK	978/14	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. Two randomised controlled studies demonstrated that after 24 weeks of treatment, umeclidinium/ vilanterol significantly improved lung function compared with an inhaled long-acting muscarinic antagonist in patients with moderate to very severe COPD. Indirect comparisons demonstrated comparable efficacy with other combinations of long acting muscarinic antagonist plus long acting beta agonist.	09.02.2015	11.02.2015	**Included** in NHS Borders formulary for the SMC approved indication
paclitaxel albumin (Abraxane®) Celgene Ltd NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	968/14	In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. In a randomised, phase III, open-label study paclitaxel albumin plus gemcitabine treatment improved median overall survival by 1.8 months compared with gemcitabine alone.	09.02.2015	11.02.2015	**Prescribing would be under SCAN regime**
	910/13	Treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia	09.02.2015	11.02.2015	**Prescribing would be under SCAN regime**

bosutinib (Bosulif®) Pfizer NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.		(Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. Major cytogenetic response was achieved in 23/52 patients who represented "unmet medical need" within a non-comparative phase I/II study, in which the full population included 546 patients with CP, AP or BP imatinib pre-treated Ph+ CML. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bosutinib. 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.			
apixaban (Eliquis) Pfizer/Bristol Myers Squibb	1029/15	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults. Two phase III studies demonstrated efficacy and safety of apixaban. One study showed non-inferiority of apixaban versus standard anticoagulant therapy including a low molecular weight heparin in combination with a vitamin K antagonist for treatment of DVT/PE with a lower rate of major and clinically relevant non-major bleeding. In a 12 month study apixaban demonstrated superiority versus placebo for the prevention of recurrent DVT/PE with a similar bleeding profile to placebo.	09.03.2015	08.04.2015	**Included** in NHS Borders formulary for the SMC approved indication
ruxolitinib (Jakavi) Novartis NB: This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	867/13	The treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. In patients with myelofibrosis, a significantly greater proportion of patients achieved a spleen response (reduction in spleen volume of at least 35% from baseline) at 48 weeks when treated with ruxolitinib compared with best available therapy. Ruxolitinib was also associated with a greater proportion of patients reporting a clinically significant reduction in myelofibrosis-related symptoms when compared with placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of ruxolitinib. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	09.03.2015	08.04.2015	**Prescribing would be under SCAN regime**
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					

Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2014 – 31st March 2015

Recommended for Restricted use within NHS Scotland – February 2015 – March 2015					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
idelalisib (Zydelig) Gilead Sciences Ltd	1026/15	In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • who have received at least one prior therapy, or • as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. SMC restriction: patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy. Idelalisib in combination with an anti-CD20 antibody significantly improves progression free survival compared with an anti-CD20 antibody alone in patients with relapsed CLL. The treatment effect across subgroups with 17p deletion and/or TP53 mutation was consistent with that of the total study population. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idelalisib. It is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	09.03.2015	08.04.2015	**Prescribing would be under SCAN regime**
ledipasvir-sofosbuvir (Harvoni) Gilead Sciences Ltd	1030/15	Treatment of chronic hepatitis C (CHC) in adults. SMC restriction: genotype 1 and 4 CHC only. In three, uncontrolled phase III studies conducted in treatment-naïve and treatment-experienced non-cirrhotic and cirrhotic patients with genotype 1 CHC, ledipasvir/sofosbuvir ± ribavirin achieved sustained virological response (at 12 weeks post treatment) rates of 93% to 99%, which were significantly superior to historical control rates. No clinical or economic data were presented for genotype 3 patients with cirrhosis and/or prior treatment failure.	09.03.2015	08.04.2015	**Included** in NHS Borders formulary for the SMC approved indication
dabrafenib (Tafinlar) GSK NB: This advice takes account of	1023/15	Monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. SMC restriction: for use in patients with unresectable or metastatic BRAFV600 mutation-positive metastatic melanoma who have received no prior therapy. In a phase III randomised open-label study, treatment with dabrafenib extended median progression free survival by 4.2 months compared with chemotherapy.	09.03.2015	08.04.2015	**Prescribing would be under SCAN regime**

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 dabrafenib. It is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.			
fosfomycin (Fomicyt) Nordic Pharma	1033/15	For the treatment of the following infections in adults and children including neonates: - Acute osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Fosfomycin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections listed above, or when these alternative antibacterial agents have failed to demonstrate efficacy. Consideration should be given to national guidance on the appropriate use of antibacterial agents. SMC restriction: initiation by microbiologists or infectious disease specialists. Unlicensed preparations of intravenous fosfomycin are commonly used in the NHS in Scotland to treat multi-drug resistant gram negative organisms. This provides a licensed preparation. Estimated patient numbers are expected to be small.	09.03.2015	08.04.2015	**Included** in NHS Borders formulary for the SMC approved indication
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – February 2015 – March 2015					
Drug Name	**SMC Number**	**Indication**	**Date SMC Advice Published**	**Date BFC Decision**	**Formulary Decision & Rationale for non-inclusion**
abiraterone (Zytiga®) Janssen-Cilag *NB* This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	873/13	With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. In a randomised, double-blind phase III study of adult men with metastatic castration-resistant prostate cancer, treatment with abiraterone in combination with corticosteroid was associated with an extended progression-free survival and overall survival when compared with placebo plus corticosteroid. The	09.02.2015	11.02.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

		submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC and in addition their justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC.			
colestilan (BindRen®) Mitsubishi Tanabe Pharma Europe Ltd	939/14	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis. Colestilan, compared with placebo, reduced serum phosphorus in dialysis patients with CKD and hyperphosphataemia. Comparative data with another non-calcium-based, non-absorbed phosphate binder suggested comparable phosphorus lowering effects but non-inferiority was not demonstrated conclusively. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by the IRP.	09.02.2015	11.02.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
cabozantinib (Cometriq) Swedish Orphan Biovitrum NB: This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1022/15	For the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma. In one pivotal, phase III study, cabozantinib was associated with a significant advantage in progression-free survival over placebo. However, the difference between cabozantinib and placebo did not reach statistical significance in the subgroup of patients with Rearranged during Transfection (RET) negative tumours. The summary of product characteristics therefore notes that for patients in whom RET mutation status is unknown or is negative, a possible lower benefit should be taken into account before individual treatment decision. 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.	09.03.2015	08.04.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

Standard Advice on NHS Borders Formulary Decisions

- **Included** in NHS Borders formulary for the SMC approved indication
- **Prescribing would be under SCAN regime**
- **Not Included** in NHS Borders formulary because NHS Borders decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question;
- NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
- Product would not be used in NHS Borders
- **Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;

- **Not recommended for use in NHS Borders - not recommended by SMC**