Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2015 – 31st March 2016

April 2015 – May 2015

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – April 2015 – May 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
aclidinium / formoterol fumarate dehydrate (Duaklir Genuair) Almirall	1034/15	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. In two 24-week comparator- and placebo-controlled phase III studies, treatment with aclidinium/formoterol 340/12 microgram resulted in statistically significant improvements in FEV1 % predicted pre-dose (versus a LABA) and post-dose (versus a LAMA).	13.04.2015	10.06.2015	**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;
ponatinib (Iclusig) Ariad Pharmaceuticals NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1032/15	Adult patients with Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. A non-comparative phase II study of ponatinib was conducted with primary outcomes of major cytogenetic response in patients with baseline chronic phase CML and major haematologic response in patients with baseline accelerated or blast phase CML or Ph+ALL. Ponatinib demonstrated efficacy in heavily pre-treated CML and Ph+ALL patients who had received dasatinib/nilotinib as second line or further line tyrosine kinase inhibitor therapy or who had the T315I mutation.	13.04.2015	10.06.2015	**Prescribing would be under SCAN regime**
sucroferric oxyhydroxide (Velphoro) Fresenius Medical Care (UK) Ltd.	1035/15	For the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD). It should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy vitamin D3 or one of its analogues, or calcimimetics to control the development of renal bone disease. After 12	13.04.2015	10.06.2015	**Not Included** in NHS Borders formulary because clinicians have not submitted an application for use in NHS Borders.

		weeks, sucroferric oxyhydroxide was non-inferior to a non-calcium, non-aluminium-based phosphate binder at lowering serum phosphorus levels in adults with CKD, receiving HD or PD.			
nintedanib (Vargatef) Boehringer Ingelheim Ltd NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1027/15	in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy. Addition of nintedanib to second-line treatment of stage IIIb/IV NSCLC with docetaxel significantly increased overall survival in the subgroup patients with adenocarcinoma tumour histology. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of nintedanib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	13.04.2015	10.06.2015	**Prescribing would be under SCAN regime**
levonorgestrel (Jaydess) Bayer	1036/15	Contraception for up to 3 years. A phase III, open-label, randomised study confirmed the contraceptive efficacy of levonorgestrel 13.5mg intrauterine delivery system according to the Pearl Index.	13.04.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
regorafenib (Stivarga) Bayer NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1031/15	Treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib. In a study of patients with metastatic or unresectable GIST who had prior treatment with imatinib and sunitinib, treatment with regorafenib prolonged the median progression free survival by 3.9 months when compared with placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of regorafenib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	13.04.2015	10.06.2015	**Prescribing would be under SCAN regime**
fingolimod (Gilenya) Novartis	1038/15	As a single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: • Patients with high disease activity despite treatment with at least one disease modifying therapy. Analysis of a subgroup of patients who had high disease activity despite prior disease modifying therapy in the year before study entry found that over a 12 month period fingolimod reduced the annualised relapse rate compared	13.04.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication

		with another disease modifying therapy by 61% in patients who received prior interferon beta, and by 50% in patients who had received any prior disease modifying therapy. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of fingolimod. 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.			
tacrolimus (Envarsus) Chiesi Limited	1041/15	Prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. Tacrolimus (Envarsus®) is suitable for use by patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy. It has increased bioavailability compared with other tacrolimus preparations. Tacrolimus (Envarsus®) has demonstrated non-inferiority to a tacrolimus immediate-release capsule and has a similar cost per equivalent dose.	13.04.2015	10.06.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;
idelalisib (Zydelig) Gilead Sciences NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1039/15	Monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment. Idelalisib demonstrated clinical activity, measured by overall response rate, in a phase II non-comparative study. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idelalisib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	11.05.2015	10.06.2015	**Prescribing would be under SCAN regime**
liraglutide (Victoza) Novo Nordisk (No.)	1044/15	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with basal insulin when this, together with diet and exercise, does not provide adequate glycaemic control. The addition of liraglutide to basal insulin in combination with another anti-diabetic agent was associated with a significant reduction in HbA1c compared with placebo and an alternative insulin regimen. Liraglutide has previously been accepted for restricted use as a third line antidiabetic agent for use in combination with oral antidiabetic agents. This now extends the advice to include its use in combination with insulin.	11.05.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication

vedolizumab (Entyvio) Takeda	1045/15	The treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. A higher proportion of patients treated with vedolizumab achieved a clinical response at week six and clinical remission at week 52 compared with placebo in a controlled phase III study. Patients who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. This advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of vedolizumab. 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. Vedolizumab is also indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. A submission for this indication is currently undergoing SMC assessment.	11.05.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
dexamethasone implant applicator (Ozurdex) Allergan	1046/15	Treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. Intravitreal dexamethasone improved visual acuity more than sham treatment in adult patients who were pseudophakic or had received prior treatment for diabetic macular oedema, based on subgroup analyses.	11.05.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
linagliptin (Trajenta) Boehringer-Ingelheim	850/13	the treatment of type 2 diabetes mellitus to improve glycaemic control in adults in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. Linagliptin, compared with placebo, improved glycaemic control in adults with type 2 diabetes who had inadequate glycaemic control on an insulin-containing regimen. SMC has previously accepted linagliptin for restricted use as monotherapy in combination with metformin, and in combination with a sulphonylurea and metformin, This now extends the	11.05.2015	10.06.2015	**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;

		advice to include its use in combination with insulin.			
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – April – May 2015					
Drug Name	SMC Number	Indication			
infliximab (Remsima) Celltrion Healthcare Hungary Kft.	1006/14	Rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function in: • adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; • adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. Infliximab (Remsima®) is also indicated in the following conditions: adult and paediatric Crohn's disease and ulcerative colitis; adult psoriatic arthritis, psoriasis and ankylosing spondylitis. ***SMC restriction:*** Infliximab (Remsima®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®]. A phase III, randomised, double-blind, parallel-group study demonstrated similar efficacy and safety of biosimilar infliximab with originator infliximab in patients with rheumatoid arthritis. Infliximab (Remsima®) is a biosimilar product to a reference product (infliximab [Remicade®]). The British National Formulary advises that it is good practice to prescribe biologic medicinal products by brand name.	13.04.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
infliximab (Inflectra) Hospira	1007/14	Rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function in: • adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; • adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. Infliximab (Inflectra®) is also indicated in the following conditions: adult and paediatric Crohn's disease and	13.04.2015	10.06.2015	**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

		ulcerative colitis; adult ankylosing spondylitis, psoriatic arthritis and psoriasis. ***SMC restriction:*** Infliximab (Inflectra®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®]. A phase III, randomised, double-blind, parallel-group study demonstrated similar efficacy and safety of biosimilar infliximab with originator infliximab in patients with rheumatoid arthritis. Infliximab (Inflectra®) is a biosimilar product to a reference product (infliximab [Remicade®]). The British National Formulary advises that it is good practice to prescribe biologic medicinal products by brand name.			
ofatumumab (Arzerra) Novartis NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1037/15	ofatumumab in combination with chlorambucil or bendamustine is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior therapy and who are not eligible for fludarabine-based therapy. SMC restriction: for use in patients who would not be considered for bendamustine therapy and who would receive chlorambucil-based therapy. The combination of ofatumumab plus chlorambucil produced a statistically and clinically significant increase in progression free survival compared with an alkylating agent alone in older patients with previously untreated CLL who had co-morbidities. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ofatumumab and it is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	11.05.2015	10.06.2015	**Not included because clinicians do not support formulary inclusion**
budesonide 3mg gastro-resistant capsules (Budenofalk) Dr Falk Pharma UK Ltd	1043/15	Autoimmune hepatitis. SMC restriction: for use in non-cirrhotic patients who are intolerant of conventional oral corticosteroids (prednisolone) with severe corticosteroid-related side effects (actual or anticipated) such as psychosis, poorly controlled diabetes or osteoporosis In a phase IIb study, a significantly greater proportion of patients with non-cirrhotic autoimmune hepatitis achieved complete biochemical remission and a reduction in predefined corticosteroid-specific side effects when treated with budesonide plus an immunosuppressant compared with an alternative corticosteroid plus an immunosuppressant.	11.05.2015	10.06.2015	**Not Included** in NHS Borders formulary (for this indication) because clinicians have not submitted an application for use in NHS Borders.
entecavir (Baraclude) Bristol Myers Squibb Pharmaceuticals	1049/15	Treatment of chronic hepatitis B virus infection in nucleoside naive paediatric patients from 2 to <18 years	11.05.2015	10.06.2015	NHS Borders would not commence treatment with this drug – but would continue treatment

Ltd		of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum alanine aminotransferase levels, or histological evidence of moderate to severe inflammation and/or fibrosis. SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases. While the benefits of viral suppression in adults are acknowledged the benefits of anti-viral treatment in children are less well established. In clinical studies, the antiviral efficacy of entecavir in children is reported to be lower than in adults. However there is a potential need for treatment in a very small number of paediatric patients and this is the first licensed medicine for hepatitis B in this age group.			initiated at specialist unit
adalimumab (HUMIRA) AbbVie Ltd	1050/15	for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Treatment of paediatric patients with adalimumab resulted in clinically relevant improvements in the number of active joints with arthritis compared with placebo at 12 weeks. Adalimumab has previously been accepted for restricted use within NHS Scotland in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).	11.05.2015	10.06.2015	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 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
collagenase clostridium histolyticum (Xiapex) Swedish Orphan Biovitrum Ltd	1059/15	Treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.	11.05.2015	10.06.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
Insulin degludec (Tresiba) Novo Nordisk Limited	1060/15	Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year. The holder of the marketing authorisation has not made a submission to	11.05.2015	10.06.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

		SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland.			

June 2015 – July 2015

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – June 2015 – July 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
ombitasvir / paritaprevir ritonavir (Viekirax) and dasabuvir (Exviera) Abbvie	1051/15	• Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with dasabuvir (Exviera®) with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults. • Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with ribavirin for the treatment of genotype 4 CHC in adults. In six phase III studies, conducted in patients with genotype 1 CHC, rates of sustained virological response at 12 weeks post-treatment were achieved in ≥96% of patients who received licensed treatment regimens of ombitasvir/paritaprevir/ritonavir + dasabuvir, irrespective of sub-genotype, previous treatment and presence of cirrhosis.	08.06.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
levonorgesterel (Levosert) Actavis	1058/15	Contraception. Heavy menstrual bleeding. Levosert® may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception. Levosert® intrauterine delivery system (IUS) contains the same total amount of levonorgestrel with the same release profile as an existing levonorgestrel-containing IUS at a lower unit cost.	08.06.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
sorafenib (Nexavar) Bayer NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1055/15	Treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine. Treatment with sorafenib demonstrated a significant, clinically relevant five-month improvement in median progression free survival compared with placebo in patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of	13.07.2015	12.08.2015	**Prescribing would be under SCAN regime**

		sorafenib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
riociguat (Adempas) Bayer NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1056/15	Pulmonary arterial hypertension (PAH): as monotherapy or in combination with endothelin receptor antagonists, for the treatment of adult patients with PAH with World Health Organisation Functional Class (WHO FC) II to III to improve exercise capacity. Efficacy has been shown in a PAH population including aetiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease. SMC restriction: for use as a PAH-specific monotherapy as an alternative treatment option to endothelin receptor antagonist (ERA) monotherapy in adult patients with PAH of WHO FC II to III. It is restricted to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or by similar specialists. Riociguat demonstrated significant improvement compared with placebo in exercise capacity, in terms of six-minute walking distance, in patients with symptomatic PAH in a phase III study. 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.	13.07.2015	12.08.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
tinzaparin sodium (Innohep) Leo Pharma	1061/15	Patients with solid tumours: Extended treatment of symptomatic venous thrombo-embolism (VTE) and prevention of its recurrence. In patients with cancer and VTE, tinzaparin was associated with rates of VTE recurrence that were not significantly different from those with a vitamin K antagonist (VKA). In a large study it was not significantly different from a VKA for a composite outcome that included symptomatic deep vein thrombosis (DVT), non-fatal and fatal pulmonary embolism (PE), incidental DVT and PE. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tinzaparin. 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.	13.07.2015	12.08.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
posaconazole (Noxafil) Merck Sharp & Dohme	1067/15	for use in the treatment of the following fungal infections in adults: • Invasive aspergillosis in patients with disease that is refractory to amphotericin B or	13.07.2015	12.08.2015	**Infusion is not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion

		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 (IFI) in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing IFI; • Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high risk of developing IFI. Posaconazole 300mg solution for infusion will generally result in higher plasma concentrations than posaconazole oral suspension and is expected to result in similar plasma concentrations as the tablet formulation. Posaconazole solution for infusion is more expensive than oral preparations. It is intended for patients who are not able to receive an oral formulation, and should be used for the minimum time required. Patients should be switched to an oral formulation of posaconazole as soon as clinically practical.			
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – June – July 2015					
Drug Name	SMC Number	Indication			
apremilast (Otezla) for plaque psoriasis Celgene	1052/15	For the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other	08.06.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication

		systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). In two phase III, randomised, placebo-controlled studies in patients with moderate to severe plaque psoriasis, a significantly greater proportion of patients who received apremilast achieved at least 75% improvement in the Psoriasis Area and Severity Index (PASI) score at 16 weeks compared with those who received placebo. **Accepted for use** *In May 2015, SMC reviewed a submission for apremilast (Otezla), for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). Following comments from the company amendments were made to the status of the advice and it was changed from Accepted for restricted use within NHS Scotland to Accepted for use within NHS Scotland.*			
apremilast (Otezla) for psoriatic arthritis Celgene	1053/15	Alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. SMC restriction: for use in adult patients with active PsA who have had an inadequate response with at least two prior DMARD therapies or who are intolerant to such therapies. In three phase III, randomised, placebo-controlled studies in patients with active psoriatic arthritis, a significantly greater proportion of patients who received apremilast achieved at least 20% improvement in the American College of Rheumatology response criteria (ACR 20) at 16 weeks compared with those who received placebo. Full Submission - Accepted Restricted *In May 2015, SMC reviewed a submission for apremilast (Otezla®), alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. Due to comments from comparator companies, minor amendments have been made to the 'Summary of clinical effectiveness issues' and the 'Cost of relevant*	08.06.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication

		comparators'. The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 05 June 2015, and published on Monday 08 June 2015.			
secukinumab (Cosentyx) Novartis Full Submission - Accepted Restricted with PAS *In May 2015, SMC reviewed a submission for secukinumab (Cosentyx ®), for the treatment of treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Due to comments post-SMC, a minor amendment have been made to the 'Cost of relevant comparators'. Revised Advice will be re-issued to NHS Boards/ADTCs on Friday 05 June 2015, and published on Monday 08 June 2015*	1054/15	For patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments. Secukinumab was superior to placebo and to a tumour necrosis factor (TNF) antagonist for improving symptoms of patients with moderate to severe plaque psoriasis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of secukinumab. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	08.06.2015	10.06.2015	**Included** in NHS Borders formulary for the SMC approved indication
linagliptin + metformin (Jentadueto) Boehringer Ingelheim	1057/15	For the treatment of adult patients with type 2 diabetes mellitus in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide adequate glycaemic control. SMC restriction: to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and the fixed doses are considered appropriate. For patients in whom combination therapy with linagliptin and metformin is appropriate, it has the potential to reduce the pill burden at no additional cost.	08.06.2015	10.06.2015	**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;
vedolizumab (Entyvio) (Crohn's disease) Takeda UK Ltd	1064/15	For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. SMC restriction: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNFα antagonist. In two clinical studies, more patients treated with vedolizumab achieved clinical remission at week 6 compared with placebo but	13.07.2015	12.08.2015	**Included** in NHS Borders formulary for the SMC approved indication

		the difference was only statistically significant in one study. One study included a maintenance phase, and significantly more patients treated with vedolizumab were in clinical remission at week 52 compared with placebo. Patients who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of vedolizumab. 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.			
adalimumab (HUMIRA) (chronic plaque psoriasis) AbbVie Ltd	1068/15	Treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. SMC restriction: Patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score of ≥10 and a Dermatology Life Quality Index (DLQI) of >10. Treatment with adalimumab in a paediatric population improves both signs and symptoms of psoriasis and quality of life.	13.07.2015	12.08.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
darunavir (Prezista) Janssen Cilag	1069/15	Once daily darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients aged 3 to 12 years and ≥15kg who are 1) treatment-naive or 2) treatment-experienced with no darunavir resistance-associated mutations, plasma-HIV-1 RNA <100,000 copies/mL, and CD4+ count >100x106 cells/L. SMC restriction: to be prescribed under the supervision of specialists in paediatric HIV. Darunavir is listed in the British National Formulary for Children in combination with other antiretroviral drugs for HIV infection in children previously treated with antiretrovirals or not previously treated with antiretroviral therapy. The Scottish Medicines Consortium has previously accepted darunavir in this indication in paediatric patients aged 12 to 17 years and at least 40kg body weight, and in combination with other antiretroviral medicinal products in antiretroviral (ART)-experienced	13.07.2015	12.08.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit

		paediatric patients from the age of 3 years and at least 15kg body weight.			
ceftobiprole medocaril (Zevtera) Basilea Pharmaceutica International Ltd	943/14	Ceftobiprole is indicated for the treatment of the following infections in adults: • Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) • Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents. SMC restriction: for use in the treatment of HAP (excluding VAP) when activity is required against suspected methicillin-resistant Staphylococcus aureus (MRSA) and Gram-negative pathogens (including Pseudomona aeruginosa, Escherichia coli and Klebsiella pneumoniae) and when combination treatment that includes vancomycin or teicoplanin is inappropriate or has not been tolerated, or when treatment modification is required, i.e. as an alternative to linezolid-based regimens. In a randomised, double-blind phase III study of patients with HAP, the clinical cure rate for empirical treatment with ceftobiprole was non-inferior to the rate associated with intravenous linezolid plus an anti-pseudomonal cephalosporin.	13.07.2015	12.08.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – June – July 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
olaparib (Lynparza) AstraZeneca NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1047/15	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 the sub-group of patients with BRCA mutation, olaparib was associated with a significantly improved progression-free survival compared with placebo.	13.07.2015	12.08.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

		Analysis of mature overall survival data is awaited. 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.			
rivaroxaban (Xarelto) Bayer Plc	1062/15	Rivaroxaban co-administered with aspirin alone or with aspirin plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers. Rivaroxaban in addition to standard care significantly reduced the occurrence of the primary composite endpoint: death from cardiovascular causes, myocardial infarction, or stroke, compared to standard care alone. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	13.07.2015	12.08.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
vinflunine (Javlor) Pierre Fabre NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	686/11	Monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen. Efficacy and safety of vinflunine have not been studied in patients with performance status ≥ 2. Vinflunine plus best supportive care was associated with improved survival when compared with best supportive care alone in the second-line treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract in patients with good performance status. 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.	13.07.2015	12.08.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
panitumumab (Vectibix®) Amgen Ltd	1082/15	Treatment of adult patients with wild-type RAS metastatic colorectal cancer first-line in combination with FOLFIRI. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHS Scotland. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of panitumumab 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.	13.07.2015	12.08.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2015 – 31st March 2016

August 2015 – September 2015

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – August – September 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
tiotropium (Spiriva) Revised Boehringer-Ingelheim	1028/15	As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta2 agonists and who experienced one or more severe exacerbations in the previous year. Two phase III RCTs demonstrated that the addition of tiotropium significantly improved lung function and increased the time to the first severe exacerbation compared with placebo in patients with uncontrolled asthma despite treatment with high dose inhaled corticosteroid and a long acting beta2 agonist.	10.08.2015	13.08.2015	**License extension of formulary medicine**
darunavir / cobicistat (Rezolsta) Janssen	1081/15	In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use. Pharmacokinetic studies have demonstrated that darunavir/cobicistat is bioequivalent (in terms of darunavir exposure) to ritonavir-boosted darunavir. No comparative efficacy studies have been reported.	10.08.2015	13.08.2015	**Included** in NHS Borders formulary for the SMC approved indication
palonosetron, 250 micrograms solution for injection (Aloxi®)	1073/15	Prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, in paediatric patients 1 month of age and older. A phase III double blind study demonstrated non-inferiority of palonosetron to another 5-HT3 antagonist in paediatric patients.	10.08.2015	13.08.2015	**Prescribing would be under SCAN regime**
aflibercept (Eylea) Bayer	1074/15	For adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion. Aflibercept was associated with significant improvements over laser in visual acuity during a 6-month, randomized, double-masked phase III study in patients with branch retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of	07.09.2015	14.10.2015	**Included** in NHS Borders formulary for the SMC approved indication

		aflibercept. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. Aflibercept has previously been accepted by SMC for macular oedema secondary to central retinal vein occlusion. This advice now extends its use to patients with macular oedema secondary to branch retinal vein occlusion.			
bortezomib (Velcade) Janssen-Cilag Ltd	1075/15	In combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation. Bortezomib in combination with rituximab, cyclophosphamide, doxorubicin and prednisone significantly improved progression-free survival compared to a regimen containing rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone in adults with previously untreated mantle cell lymphoma who were unsuitable for haematopoietic stem cell transplantation.	07.09.2015	14.10.2015	**Prescribing would be under SCAN regime**
sitagliptin (Januvia) MSD	1083/15	The treatment of type 2 diabetes mellitus to improve glycaemic control in adults as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control. Sitagliptin, compared with placebo, improved glycaemic control in adults with type 2 diabetes mellitus who had inadequate glycaemic control on an insulin-containing regimen. SMC has previously accepted sitagliptin for use in combination with a sulfonylurea (with or without metformin), and for restricted use with metformin and as monotherapy. This now extends the advice to include its use in combination with insulin.			**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
pasireotide (as pamoate), 20mg, 40mg 60mg powder and solvent for suspension for injection (Signifor) Novartis Pharmaceuticals UK Ltd.	1048/15	Treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue. Pasireotide administered every four weeks was significantly superior to an active control group (comprising other somatostatin analogues administered monthly) for the primary endpoint of biochemical control, in patients with inadequately controlled acromegaly following treatment with a somatostatin analogue for at least six months.	07.09.2015	14.10.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit

		This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			
lisdexamfetamine dimesylate, 30mg, 50mg and 70mg hard capsules (Elvanse Adult) Shire Pharmaceuticals Ltd	1079/15	As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults. Based on clinical judgment, patients should have ADHD of at least moderate severity. Three phase III and two phase IV clinical studies in adults with ADHD demonstrated that lisdexamfetamine improves the symptoms of ADHD compared with placebo.	07.09.2015	14.10.2015	**License extension of formulary medicine**
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – August – September 2015					
Drug Name	SMC Number	Indication			
tedizolid phosphate (Sivextro) Cubist (UK) Limited	1080/15	The treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. SMC restriction: • Use in patients with ABSSSI caused by Gram-positive Staphylococcus aureus (specifically methicillin-resistant Staphylococcus aureus [MRSA] isolates) • Use of tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacterial on the specific advice of local microbiologists or specialists in infectious disease. In two randomised, double-blind clinical studies, tedizolid phosphate was non-inferior to another oxazolidinone antibacterial in adult patients with ABSSSI. The presenting company did not submit any evidence for SMC to consider around the use of tedizolid phosphate in "mixed infections", where the infection involves both Gram-positive and Gram-negative organisms.	10.08.2015	13.08.2015	**Not Included** in NHS Borders formulary because clinicians have not submitted an application for use in NHS Borders.
bevacizumab (Avastin) Roche Products Limited NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1063/15	In combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents. SMC restriction: to use in combination with paclitaxel. The addition of bevacizumab to chemotherapy improved progression free survival in patients with platinum-resistant ovarian cancer in an open-label phase III	07.09.2015	14.10.2015	**Prescribing would be under SCAN regime**

		randomised study.This SMC 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 PAS in NHS Scotland or a list price that is equivalent or lower.			
ledipasvir/sofosbuvir (Harvoni) Gilead Sciences	1084/15	Treatment of genotype 3 chronic hepatitis C (CHC) in adults. SMC restriction: patients who are ineligible for or unable to tolerate interferon. Efficacy data are limited to a phase II open-label study. The addition of ledipasvir to sofosbuvir plus ribavirin is expected to increase antiviral activity, although the magnitude of this effect is not well characterised. SMC has previously accepted ledipasvir/sofosbuvir for restricted use in genotype 1 and 4 CHC; this now extends advice to include use in genotype 3 CHC.	07.09.2015	14.10.2015	**License extension of formulary medicine**
tafluprost 15micrograms/mL and timolol 5mg/mL preservative-free eye drops (Taptiqom®) Santen GmbH	1085/15	Reduction of intraocular pressure in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative-free eye drops. SMC restriction: to use in patients who have proven sensitivity to preservatives. The combination product costs less than preservative-free tafluprost and timolol eye drops administered separately.	07.09.2015	14.10.2015	**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
insulin glargine 300 units/mL solution for injection in a pre-filled pen (Toujeo) Sanofi	1078/15	Treatment of type 1 or type 2 diabetes mellitus in adults aged 18 years and above. SMC restriction: Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections. Insulin glargine 300 units/mL (Toujeo®) has similar efficacy but is not bioequivalent to insulin glargine 100 units/mL and therefore not interchangeable without dose adjustment. At doses that provide comparable glycaemic control, Toujeo® is available at a similar cost to insulin glargine 100 units/mL.	07.09.2015	14.10.2015	**Included** in NHS Borders formulary
SMC MEDICINES NOT RECOMMENDED					

Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2015 – 31st March 2016

Is Not Recommended for use within NHS Scotland – August – September 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
eribulin (Halaven) Eisai NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1065/15	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. In a randomised, phase III, open-label study, patients treated with eribulin gained 2.5 months additional overall survival compared with the comparator, treatment of physicians choice, which included a range of single agent chemotherapy treatments. The submitting company's justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC. This supersedes previous advice for eribulin (SMC No. 726/11).	10.08.2015	13.08.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
enzalutamide (Xtandi) Astellas Pharma Ltd NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1066/15	Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. In a randomised phase III study of adult men with chemotherapy naive mCRPC treatment with enzalutamide was associated with an extended radiographic progression free survival and overall survival compared to placebo. The 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.	10.08.2015	13.08.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
elosulfase alfa (Vimizim) BioMarin Europe Ltd NB This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	1072/15	Treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages. In a double-blind placebo-controlled study the difference from baseline in the mean distance walked in the 6-minute walking test was significantly longer for elosulfase alfa, given weekly, than placebo at week 24. 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.	07.09.2015	14.10.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

avanafil (Spedra) A Menarini Farmaceutica Internazionale SRL	980/14	Treatment of erectile dysfunction (ED) in adult men. In order for avanafil to be effective, sexual stimulation is required. The pivotal studies demonstrated a statistically significant improvement in ED after administration of avanafil compared with placebo in the general ED population and in patients with ED due to diabetes or following radical prostatectomy. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	07.09.2015	14.10.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
ketoconazole (Ketoconazole HRA) HRA Pharma	1100/15	Treatment of endogenous Cushing's syndrome in adults and adolescents above the age of 12 years. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	07.09.2015	14.10.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
tigecycline Tygacil) Pfizer Limited	1101/15	Treatment in children from the age of eight years for the following infections: • complicated skin and soft tissue infections, excluding diabetic foot infections • complicated intra-abdominal infections The holder of the 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.	07.09.2015	14.10.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

October 2015 – November 2015

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – October – November 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
radium 223 (Xofigo) Bayer NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1077/15	for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. In a randomised phase III study of adult men with castration-resistant prostate cancer with symptomatic bone metastases and no known visceral metastases, treatment with radium-223 dichloride was associated with a significant improvement in overall survival compared to placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of radium-223 dichloride. This advice is contingent upon the continuing availability	12.10.2015	14.10.2015	**Prescribing would be under SCAN regime**

		of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.			
ciclosporin eye drops (Ikervis) Santen GmBH	1089/15	Treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes. Ciclosporin eye drops, compared to vehicle, improved signs of corneal surface damage but not symptoms in patients with severe keratitis associated with dry eye disease. *(Indication updated 12.10.15)*	12.10.2015	14.10.2015	**Included** in NHS Borders formulary for the SMC approved indication
travoprost (Travatan) Alcon Laboratories	1091/15	Decrease of elevated intraocular pressure in paediatric patients aged 2 months to <18 years with ocular hypertension or paediatric glaucoma. In a randomised, double-masked study of paediatric patients with glaucoma or ocular hypertension, travoprost was demonstrated to be non-inferior to a beta blocker eye drop preparation in terms of mean reduction in intra-ocular pressure. Another topical ocular prostaglandin analogue preparation is licensed for use in children for this indication and is considerably cheaper. In reducing intra-ocular pressure, travoprost is comparable in effect to other drugs in its class.	12.10.2015	14.10.215	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
midodrine hydrochloride (Bramox®) Brancaster Pharma Limited	1094/15	In adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate. Midodrine hydrochloride (Bramox®) 5mg tablets have been shown to be bioequivalent to the unlicensed midodrine 5mg product currently in use in NHS Scotland. The availability of midodrine hydrochloride (Bramox®) will allow the prescribing of a licensed medicinal product, with a resultant small net budget impact, based on estimates from primary and secondary prescribing and expenditure data from 2013/14.	12.10.2015	14.10.2015	**Included** in NHS Borders formulary for the SMC approved indication
abiraterone (Zytiga) Janssen-Cilag NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	873/13	Abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) 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 chemotherapy-naive mCRPC, treatment with abiraterone acetate in combination with corticosteroid was associated with a statistically significant extended progression-free survival and overall survival when compared with placebo plus	12.10.2015	14.10.2015	**Prescribing would be under SCAN regime**

		corticosteroid. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone acetate. 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.			
pembrolizumab (Keytruda) Merck, Sharpe & Dohme NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1086/15	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab. In a phase III randomised open-label study, treatment with pembrolizumab (at unlicensed doses) extended median progression free survival and overall survival compared with other immune therapy in patients with advanced melanoma previously untreated with ipilimumab. 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 patient access scheme in NHS Scotland or a list price that is equivalent or lower. SMC has also assessed pembrolizumab as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults previously treated with ipilimumab and has advised that it is not recommended for use within NHS Scotland in this setting (SMC No.1087/15).	09.11.2015	11.11.2015	**Prescribing would be under SCAN regime**
edoxaban (Lixiana) – VTE Daiichi Sankyo	1090/15	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. One phase III study showed non-inferiority of edoxaban versus a vitamin K antagonist for venous thromboembolism recurrence in patients who had received at least five days treatment with low molecular weight heparin or unfractionated heparin. Edoxaban was also associated with a significant reduction in the risk of major and clinically relevant non-major bleeding (composite endpoint).	09.11.2015	11.11.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;
edoxaban (Lixiana) – NVAF Daiichi Sankyo	1095/15	For prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA). One phase III study showed non-inferiority of edoxaban versus a vitamin K antagonist for the prevention of stroke and	09.11.2015	11.11.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;

		systemic embolism in adult patients with NVAF and a CHADS2 score of ≥2. It was also associated with a significant reduction in risk of major bleeding.			
atazanavir & cobicistat (Evotaz) BMS	1098/15	In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir. Pharmacokinetic studies have demonstrated that atazanavir plus cobicistat is bioequivalent (in terms of atazanavir exposure) to ritonavir-boosted atazanavir. For patients in whom atazanavir is an appropriate treatment, atazanavir/cobicistat (Evotaz®) provides a combination product at a small cost premium compared to ritonavir-boosted atazanavir.	09.11.2015	11.11.2015	**Included** in NHS Borders formulary for the SMC approved indication
tiotropium + olodaterol (Spiolto Respimat) Boehringer Ingelheim	1099/15	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Spiolto® Respimat® should be used in patients for whom tiotropium and olodaterol are appropriate choices of antimuscarinic and long-acting beta2-agonist respectively. Tiotropium/olodaterol (Spiolto® Respimat®) is available at a lower cost than the individual inhalers given separately.	09.11.2015	11.11.2015	**Not Included** in NHS Borders formulary because clinicians do not support the formulary inclusion;
triamcinolone (Hexacetonide) Intrapharm Laboratories Ltd	1103/15	Juvenile idiopathic arthritis (JIA). This submission relates to a new licence extension for JIA where previously an unlicensed preparation has been used. This is the first intra-articular corticosteroid licensed for JIA.	09.11.2015	11.11.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – October – November 2015					
Drug Name	SMC Number	Indication			
nintedanib (Ofev) Boehringer-Ingelheim NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1076/15	In adults for the treatment of idiopathic pulmonary fibrosis (IPF). SMC restriction: For use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%. Nintedanib, compared to placebo, reduces the decline in pulmonary function assessed by forced vital capacity in patients with IPF. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nintedanib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. *(Indication updated 12.10.15)*	12.10.2015	14.10.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
insulin degludec/liraglutide (Xultophy) Novo Nordisk A/S	1088/15	Treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or	12.10.2015	14.10.2015	**Included** in NHS Borders formulary

		combined with a GLP-1 receptor agonist or with basal insulin do not provide adequate glycaemic control. SMC restriction: for use in patients who are uncontrolled on basal insulin analogues (glycosylated haemoglobin [HbA1c] >7.5% [59mmol/mol]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin to obtain glucose control. In two phase III studies treatment with insulin degludec/liraglutide resulted in a significant reduction from baseline to week 26 in HbA1c compared with the basal insulin comparators.			
trastuzumab (Herceptin) Roche Products Ltd. Note: HER2 FISH (not Immunohistochemistry) testing is currently available as part of the Molecular Pathology Laboratory Consortium arrangements for all patients in Scotland requiring such a test. NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	623/10	In combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. It is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay. SMC restriction: for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser"). The addition of trastuzumab to doublet chemotherapy improved overall and progression-free survival and tumour response.	12.10.2015	14.10.2015	**Prescribing would be under SCAN regime**
empagliflozin/metformin (Synjardy) Boehringer Ingelheim	1092/15	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 inadequately controlled on their maximally tolerated dose of metformin alone • in patients inadequately controlled with metformin in combination with other glucose-lowering medicinal products, including insulin • in patients already being treated with the combination of empagliflozin and metformin as separate tablets. SMC restriction: • for use in patients for whom this fixed dose combination of empagliflozin and metformin is considered appropriate. • for use as dual therapy (empagliflozin and metformin) when a sulphonylurea is inappropriate.	12.10.2014	14.10.2014	**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

		Empagliflozin/metformin (Synjardy®) has the potential to reduce the pill burden at no additional cost.			
bevacizumab (Avastin) Roche Products Limited 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 IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. SMC restriction: In patients with FIGO stage IV disease. Addition of bevacizumab to standard chemotherapy with carboplatin and paclitaxel increased progression-free survival.	09.11.2015	11.11.2015	**Prescribing would be under SCAN regime**
raltegravir (granules for oral suspension) (Isentress) MSD	1102/15	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks. SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir granules should be prescribed under the supervision of specialists in paediatric HIV. The granules for oral suspension are licensed for use in patients weighing 3kg to 20kg and provide an alternative formulation for infants where chewable tablets are not suitable. Because the formulations are not bioequivalent, neither the granules for oral suspension nor the chewable tablets should be substituted for the 400 mg film-coated tablet. SMC has previously accepted raltegravir 25mg and 100mg chewable tablets and raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.	09.11.2015	11.11.2015	**Included** in NHS Borders formulary for the SMC approved indication
raltegravir (chewable tablets) (Isentress) MSD	1113/15	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in children from the age of 4 weeks to <2 years. SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir chewable tablets should be prescribed under the supervision of specialists in paediatric HIV. The chewable tablets are not	09.11.2015	11.11.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit

		bioequivalent to the film-coated tablets and therefore are not interchangeable. SMC has previously accepted raltegravir 25mg and 100mg chewable tablets and raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.			
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – October – November 2015					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
everolimus (Afinitor) Novartis Pharmaceuticals UK Ltd NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	(872/13	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. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	12.10.2015	14.10.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
budesonide (Cortiment) Ferring Pharmaceuticals	1093/15	In adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient. In two, phase III, placebo-controlled studies, significantly higher proportions of patients achieved clinical and colonoscopic remission at week 8 with budesonide (Cortiment®) 9mg once daily compared to placebo. However, similar clinical effectiveness with the reference product, a rectal formulation of budesonide, has not been demonstrated.	12.10.2015	14.10.215	**Not recommended for use in NHS Borders - not recommended by SMC**
pembrolizumab (Keytruda) Merck, Sharpe & Dohme NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1087/15	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.	09.11.2015	11.11.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

		The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. SMC has also assessed pembrolizumab as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults previously untreated with ipilimumab and has advised that it is accepted for use within NHS Scotland in this setting.			
regorafenib (Stivarga) 40mg film-coated tablets Bayer Plc SMC	1118/15	Adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available 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.	09.11.2015	11.11.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
everolimus (Certican) 0.25mg, 0.5mg and 0.75mg tablets Novartis Pharmaceuticals UK Ltd SMC	1117/15	• Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a cardiac transplant • Prophylaxis of organ rejection in patients receiving a hepatic transplant The holder of the 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 everolimus for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal transplant and therefore SMC has not issued advice for that indication.	09.11.2015	11.11.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

December 2015 – January 2016

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – December 2015 – January 2016					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
ceritinib (Zykadia) Novartis NB: This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1097/15	Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib. In two non-comparative studies (one phase I and one phase II) of patients with advanced ALK-positive NSCLC	07.12.2015	09.12.2015	**Prescribing would be under SCAN regime**

		previously treated with crizotinib, treatment with ceritinib was associated with clinically meaningful tumour responses and median overall survival of approximately 15 to 17 months. Controlled data with clinical outcomes are currently lacking. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ceritinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
naloxegol (Moventig) AstraZeneca	1106/15	The treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s). Naloxegol compared to placebo significantly improved the response rate in patients with opioid-induced constipation including patients who had previously had an inadequate response to at least four days of treatment with at least one class of laxative.	07.12.2015	09.12.2015	**Included** in NHS Borders formulary for the SMC approved indication
glatiramer acetate (Copaxane) 40mg/mL injection Teva UK Limited	1108/15	Treatment of relapsing forms of multiple sclerosis (MS). This new formulation of glatiramer actetate (40mg/ml) given three times a week costs the same as the currently available formulation (glatiramer acetate 20mg/ml) that is given daily.	07.12.2015	09.12.2015	**Not Included** in NHS Borders formulary because clinicians have not submitted an application for use in NHS Borders.
efavirenz (Sustiva) Bristol Myers Squibb	1125/15	Antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3.5kg. For patients at least 3 months old and weighing at least 3.5kg who cannot swallow capsules, the capsule contents can be administered with a small amount of food using the capsule sprinkle method of administration. Efavirenz is listed in the British National Formulary for Children for the treatment of HIV infection.	07.12.2015	09.12.2015	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit
tolvaptan (Jinarc) Otsuka NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1114/15	To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease. In a phase III placebo-controlled study tolvaptan, after 3 years, had significantly slowed the rate of disease progression as measured by impact on the rate of increase in total kidney volume (TKV) in ADPKD patients who were deemed to be at high risk of disease progression and had relatively preserved renal function. The study inclusion criteria included (list not exhaustive): age 18 to 50 years old, TKV ≥750ml and creatinine clearance ≥60ml/minute.	11.01.2016	10.02.2016	NHS Borders would not commence treatment with this drug – but would continue treatment initiated at specialist unit

		This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tolvaptan. This advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.			
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – December 2015 – January 2016					
Drug Name	SMC Number	Indication			
lenalidomide (Revlimid) Celgene NB: This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1096/15	Treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. SMC restriction: for use in patients unsuitable for thalidomide-containing regimens. Continuous lenalidomide plus low-dose dexamethasone, compared with melphalan, prednisolone plus thalidomide, significantly improved progression-free survival in treatment-naive patients with newly diagnosed multiple myeloma who were not eligible for transplant. Overall survival data are immature, but interim analyses suggest a survival benefit for lenalidomide plus low-dose dexamethasone compared with melphalan, prednisolone plus thalidomide. This submission focuses on lenalidomide in combination with dexamethasone. Lenalidomide is also licensed for use in combination with melphalan and prednisolone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. The submitting company did not provide evidence for SMC assessment therefore SMC cannot recommend this combination for use in this treatment setting.	07.12.2015	09.12.2015	**Prescribing would be under SCAN regime**
ivermectin 10mg/g cream (Soolantra) Galderma	1104/15	Topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients. SMC restriction: the treatment of moderate to severe inflammatory lesions of rosacea where a topical treatment is considered appropriate. A phase III, randomised study demonstrated ivermectin 10mg/g cream was significantly superior to an antimicrobial cream at reducing the percentage of inflammatory lesions from baseline to week 16. The submitting company did not submit evidence for SMC assessment for use in patients with mild papulopustular rosacea, therefore SMC cannot recommend ivermectin 10mg/g cream for use in this sub-population.	07.12.2015	09.12.2015	**Included** in NHS Borders formulary for the SMC approved indication
gefitinib 250 mg tablets (Iressa)	615/10	The treatment of adult patients with locally advanced or	07.12.2015	09.12.2015	**Not Included** in NHS Borders formulary because

AstraZeneca		metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK). SMC restriction: in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy. In patients with EGFR mutation-positive, advanced NSCLC, randomised controlled studies demonstrated an improvement in the progression-free survival and tumour response rates for those treated with gefitinib compared with platinum-doublet chemotherapy. There was no overall survival benefit demonstrated. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of gefitinib. 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.			clinicians have not submitted an application for use .
atomoxetine (Strattera) oral solution Eli Lilly	1107/15	Treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD. SMC restriction: to use in patients who are unable to swallow capsules. Atomoxetine oral solution demonstrated bioequivalence to atomoxetine capsules. The availability of the oral solution will provide a formulation acceptable to patients who cannot swallow capsules. Any overall budget impact is likely to be small.	07.12.2015	09.12.2015	**Extension of license and approval for formulary medication**
netupitant/palonostron (Akynzeo®) Chugai Pharma UK	1109/15	In adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy. SMC restriction: prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. In patients receiving a first course of highly emetogenic cisplatin-based chemotherapy, treatment with netupitant/palonosetron plus dexamethasone resulted in a significantly higher proportion of patients achieving no emesis and no breakthrough medication compared with palonosetron plus dexamethasone. This advice takes account of the benefits of Patient Access Scheme (PAS) that improves the cost-effectiveness of netupitant/palonosetron. This	11.01.2016	10.02.2016	**Prescribing would be under SCAN regime**

		advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.			
dulaglutide (Trulicity) (triple therapy) Eli Lilly	1110/15	In adults with type 2 diabetes mellitus to improve glycaemic control as add-on 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: as part of a triple therapy in patients with inadequate glycaemic control on two oral anti-diabetic drugs, as an alternative glucagon-like peptide 1 (GLP-1) agonist option. Dulaglutide 1.5mg once weekly significantly reduced glycosylated haemoglobin (HbA1c) compared with a twice daily GLP-1 agonist and compared with a long-acting basal insulin analogue in patients with inadequate glycaemic control on two oral anti-diabetic drugs. Dulaglutide is also indicated for adults with type 2 diabetes mellitus to improve glycaemic control as monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. SMC has not reviewed dulaglutide in this indication and cannot recommend its use within NHS Scotland.	11.01.2016	10.02.2016	**Included** in NHS Borders formulary for the SMC approved indication
sorafenib 200mg tablets (Nexavar) Bayer plc NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	482/08	The treatment of hepatocellular carcinoma. SMC restriction: in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies. In a phase III study in patients with advanced hepatocellular carcinoma, sorafenib was superior to placebo in terms of overall survival, but not for time to symptomatic progression. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sorafenib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	11.01.2016	10.02.2016	**Prescribing would be under SCAN regime**
ustekinumab 45mg solution for injection and prefilled syringe (Stelara®) Janssen Ltd	1115/15	Treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. SMC restriction: continued treatment should be restricted to patients who achieve at least 75% improvement in their Psoriasis Area and Severity Index (PASI 75) within 16 weeks. Ustekinumab has previously been accepted for	11.01.2016	10.02.2016	**Extension of license for formulary medication**

		restricted use in adults for this indication. For the small number of adolescent patients weighing >100kg that require a dose of 90mg, a 90mg prefilled syringe is available at the same price as the 45mg prefilled syringe.			
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – December 2015 – January 2016					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
co-careldopa (Duodopa) intestinal gel Abbvie NB: This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	316/06	Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. In a phase III, 12-week study, co-careldopa intestinal gel significantly reduced 'off' time compared with oral levodopa plus a dopa decarboxylase inhibitor.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.	07.12.2015	09.12.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
anakinra (Kineret®) 100mg solution for injection in a pre-filled syringe Swedish Orphan Biovitrum Ltd	1115/15	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above, including: • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Muckle-Wells Syndrome (MWS) • Familial Cold Autoinflammatory Syndrome (FCAS) The holder of the 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.	07.12.2015	09.12.2015	**Not recommended for use in NHS Borders - not recommended by SMC**
denosumab (Xgeva)®) 120mg solution for injection Amgen Ltd	1116/15	Adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity. The holder of the 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.	07.12.2015	09.12.2015	**Not recommended for use in NHS Borders - not recommended by SMC**

Recommendations on NEW DRUGS from the Borders Formulary Committee (BFC) Following Scottish Medicines Consortium (SMC) Advice -1st APRIL 2015 – 31st March 2016

February 2016 – March 2016

SMC RECOMMENDED MEDICINES FOR USE					
Recommended for use within NHS Scotland – February 2016 – March 2016					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
guanfacine hydrochloride (Intuniv) Shire Pharmaceutical Contracts Ltd	1123/16	Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures. Two phase III studies in children and adolescents aged 6 to 17 years with ADHD demonstrated that guanfacine improved the symptoms of ADHD compared with placebo.	08.02.2016	10.02.2016	**Not Included** in NHS Borders formulary .
golimumab (Simponi) Merck, Sharpe & Dohme Ltd	1124/16	Treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). Golimumab, compared to placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of golimumab. 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.	08.02.2016	10.02.2016	**Included** in NHS Borders formulary for the SMC approved indication
panobinostat (Farydak) Novartis Pharmaceuticals UK Ltd	1122/16	In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent. In patients with relapsed or relapsed and refractory multiple myeloma, panobinostat in combination with bortezomib plus dexamethasone was associated with a significant benefit in progression-free survival (PFS) compared with bortezomib plus dexamethasone. The treatment effect of the panobinostat containing regimen on PFS was greater in the subgroup	08.02.2016	10.02.2016	**Prescribing would be under SCAN regime**

		of patients' representative of the licensed indication. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of panobinostat. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.			
ulipristal acetate (Esmya) Gedeon Richter	1128/16	For the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. A phase III study demonstrated that treatment with the licensed dose of ulipristal acetate controlled uterine bleeding in approximately three-quarters of patients with symptomatic uterine fibroids after four intermittent treatment courses.	08.02.2016	10.02.2016	**Included** in NHS Borders formulary for the SMC approved indication
fulvestrant 250mg injection(Faslodex) AstraZeneca NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting	114/04	For the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen. In a phase III randomised double blind study, fulvestrant 500mg increased progression free survival and overall survival compared to fulvestrant 250mg. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fulvestrant. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	08.02.2016	10.02.2016	**Prescribing would be under SCAN regime**
sacubitril/valsartan (Entresto) Novartis	1132/16	In adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction. Sacubitril/valsartan, compared to an angiotensin-converting enzyme inhibitor, significantly reduced rates of the composite outcome of cardiovascular death and hospitalisation for heart failure, rates of the component outcomes and of all cause mortality.	07.03.2016	13.04.2016	**Included** in NHS Borders formulary for the SMC approved indication
oseltamivir (Tamiflu®) Roche Products Limited	1127/16	Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms. Oseltamivir is listed in the British National Formulary for Children (November 2015) for use in children aged <1 year including neonates. Oseltamavir has previously been accepted for use for this indication in patients aged ≥1 year in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE	07.03.2016	13.04.2016	**Extension of license for formulary medication**

		Multiple Technology Appraisal No. 168 was valid for Scotland.			
enzalutamide (Xtandi) Astellas Pharma Ltd NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1066/15	Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) 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 chemotherapy naive mCRPC treatment with enzalutamide was associated with a statistically significant extended overall survival and radiographic progression free survival compared to placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of enzalutamide. 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.	07.03.2016	13.04.2016	**Prescribing would be under SCAN regime**
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE					
Recommended for Restricted use within NHS Scotland – February 2016 – March 2016					
Drug Name	SMC Number	Indication			
eribulin (Halaven) Eisai Ltd NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	1065/15	For the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. SMC restriction: for use in patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated. In a randomised, phase III, open-label study, median overall survival was extended by 2.5 months in patients treated with eribulin compared with the comparator, treatment of physician's choice, which included a range of single agent chemotherapy treatments. In the subgroup of patients previously treated with capecitabine the extension to median overall survival was 2.9 months. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eribulin. This advice is contingent upon the continuing availability of the PAS in NHS Scotland	07.03.2016	13.04.2016	**Prescribing would be under SCAN regime**

		or a list price that is equivalent or lower.			
insulin detemir (Levemir) Novo Nordisk Ltd	1126/16	For treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. SMC restriction: in patients unable to achieve good glycaemic control with established insulins. Insulin detemir has previously been accepted for restricted use by SMC in adults, adolescents and children from 2 years of age. Insulin detemir is included in the British National Formulary for Children (November 2015).	07.03.2016	13.04.2016	**Extension of license for formulary medication**
SMC MEDICINES NOT RECOMMENDED					
Is Not Recommended for use within NHS Scotland – February 2016 – March 2016					
Drug Name	SMC Number	Indication	Date SMC Advice Published	Date BFC Decision	Formulary Decision & Rationale for non-inclusion
eculizumab (Soliris) aHUS Alexion Pharma UK NB This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	767/12	In adults and children for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS). Four phase II, open-label, single-arm studies demonstrated the beneficial treatment effect of eculizumab on haematological parameters, renal function and thrombotic microangiopathy events. 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.	08.02.2016	10.02.2016	**Not recommended for use in NHS Borders - not recommended by SMC**
pixantrone (Pixuvri) 29 mg power for concentrate for solution for infusion	1138/16	As monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non Hodgkin B-cell Lymphomas. The holder of the 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.	08.02.2016	10.02.2016	**Not recommended for use in NHS Borders - not recommended by SMC**
teduglutide (Revestive) 5mg power and solvent for solution for injection	1139/16	For the treatment of adult patients with Short Bowel Syndrome. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	08.02.2016	10.02.2016	**Not recommended for use in NHS Borders - not recommended by SMC**
nivolumab (Opdivo) Bristol-Myers Squibb Pharmaceutical NB This advice takes account of the views from a Patient and Clinician Engagement (PACE)	1120/16	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. 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.	07.03.2016	13.04.2016	**Not recommended for use in NHS Borders - not recommended by SMC**

meeting.		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 submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.			
pertuzumab (Perjeta) Roche Products Ltd NB This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	1121/16	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.	07.03.2016	13.04.2016	**Not recommended for use in NHS Borders - not recommended by SMC**
capsaicin (Qutenza®) 179mg cutaneous patch Astellas Pharma Ltd	1140/16	Treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	07.03.2016	13.04.2016	**Not recommended for use in NHS Borders - not recommended by SMC**
daptomycin (Cubicin®) powderfor concentrate for solution for injection or infusion Novartis Pharmaceuticals UK Ltd	1141/16	Treatment of paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections. The holder of the 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.	07.03.2016	13.04.2016	**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**
- **Not Included** in NHS Borders formulary because clinicians have not submitted an application for use in NHS Borders.