



BORDERS FORMULARY COMMITTEE
SMC DECISIONS FROM JUNE 2012

SMC ACCEPTED MEDICINE			
<i>Recommended for use within NHS Scotland – Embargoed 11th November 2013</i>			
	Indication	Formulary Decision & Rationale for non-inclusion	Date
855/13 Axitinib 1mg & 5mg film coated tablets	Under review for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.	Would be prescribed under SCAN regime	December 2013
907/13 Ranibizumab 10mg/ml solution for injection	Under review treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults. In patients with choroidal neovascularisation secondary to pathologic myopia, Ranibizumab intravitreal injection was associated with a significant improvement in visual acuity of 8.4 Early Treatment Diabetic Retinopathy Study letters at three months compared with photodynamic therapy.	Included in NHS Borders formulary for the SMC approved indication	December 2013
909/13 Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg 80mg and 100mg caps	For the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed. Short term studies in adults have shown that Atomoxetine improves symptoms of ADHD compared to placebo.	Included in NHS Borders formulary for the SMC approved indication	December 2013
911/13 Enzalutamide 40mg soft capsules	For the treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy. In one randomised double blind phase 111 clinical study enzalutamide significantly increased overall survival compared with placebo.	Would be prescribed under SCAN regime	December 2013

914/13 Sodium phenylbutyrate granules 483mg/g	For adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase ornithine transcarbamylase or argininosuccinate synthetase. It is indicated in all patients with neonatal-onset presentation (complete enzyme deficiencies presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies presenting after the first month of life) who have a history of hyperammonaemic encephalopathy.	Treatment would not be initiated in NHS Borders but NHS Borders would continue treatment	December 2013
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
<i>Recommended for Restricted use within NHS Scotland – Embargoed 11th November 2013</i>			
912/13 Ondansetron 4mg, 8mg orodispersible films	Indication under review in adults and in paediatric populations.	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	December 2013
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – 11th November 2013</i>			
910/13 Bosutinib 100mg, 500mg film-coated tabs	For the treatment of adult patients with chronic phase accelerated phase and blast phase Philadelphia chromosome positive chronic myelogenous leukaemia (PH+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom Imatinib, nilotinib and dasatinib are not considered appropriate treatment options.	Not recommended for use in NHS Borders - not recommended by SMC	December 2013
925/13 Lapatinib 250mg film coated tabs	For the treatment of adult patients with breast cancer whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.	Not recommended for use in NHS Borders - not recommended by SMC	December 2013
926/13 Canakinumab 150mg powder for solution for injection	For the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.	Not recommended for use in NHS Borders - not recommended by SMC	December 2013
SMC ACCEPTED MEDICINE			
<i>Recommended for use within NHS Scotland – Embargoed Until 9th September 2013</i>			
	Indication	Formulary Decision & Rationale for non-inclusion	Date

814/12 Caffeine citrate 20mg/ml solution for infusion and oral solution.	For the treatment of primary apnoea of premature newborns.	Included in NHS Borders formulary for the SMC approved indication	October 2013
865/13 Crizotinib 200mg & 250mg hard caps.	For the treatment of adults with previously treated anaplastic lymphoma kinase (ALK-positive advanced non-small cell lung cancer (NSCLC)	Would be prescribed under SCAN regime	October 2013
889/13 Ursodeoxycholic acid 500mg film-coated tabs	For the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on x-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s).	Included in NHS Borders formulary for the SMC approved indication	October 2013
893/13 Rifaximin 550mg film-coated tabs	For the reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥ 18 years of age.	Included in NHS Borders formulary for the SMC approved indication	October 2013
895/13 Granisetron 3.1mg/24 hours transdermal patch	For the use in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	
896/13 Medroxyprogesterone acetate 104mg/0.65ml suspension for subcutaneous depot injection.	For long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	October 2013

Recommended for use within NHS Scotland – Embargoed Until 7th October 2013

899/13 Carglumic Acid 200mg dispersible tabs	For hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.	Would not be commenced in NHS Borders – but prescription would continue if commenced at tertiary centre.	October 2013
916/13 Botulinum toxin type A 50, 100, 200 allergan units/vial	For the management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required.	Not relevant in NHS Borders – service not currently available	October 2013

917/13 Nalmefene 18mg film-coated tabs	For the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	October 2013
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
<i>Recommended for Restricted use within NHS Scotland – Embargoed Until 12th August 2013</i>			
888/13 Abatacept 125mg/ml solution for subcutaneous injection in prefilled syringe	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.	Included in NHS Borders formulary for the SMC approved indication	October 2013
<i>Recommended for Restricted use within NHS Scotland – Embargoed Until 9th September 2013</i>			
891/13 Aripiprazole 5mg, 10mg, 15mg, 30mg tabs & 10mg, 15mg orodispersible tabs, 1mg/ml oral sol	For treatment up to 12 weeks of moderate to severe manic episodes in Bipolar 1 Disorder in adolescents aged 13 years and older.	Included in NHS Borders formulary for the SMC approved indication	October 2013
894/13 Rituximab 100mg, 500mg solution for infusion	In combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA).	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	October 2013
900/13 Tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tabs	In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents.	Would not be commenced in NHS Borders – but prescription would continue if commenced at tertiary centre.	October 2013
901/13 Etravirine 25mg, 100mg, 200mg tabs	In combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age.	Would not be commenced in NHS Borders – but prescription would continue if commenced at tertiary centre.	October 2013
902/13 Raltegravir 25mg, 100mg chewable & 400mg film-	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years.	Would not be commenced in NHS Borders – but prescription would	October 2013

coated tabs		continue if commenced at tertiary centre.	
903/13 Lixesenatide 10mcgm/02ml. 20mcgm/0.2ml sol for inj in pre-filled disposable pen	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.	Included in NHS Borders formulary for the SMC approved indication	October 2013
904/13 Tenofovir disoproxil (as fumarate) 245mg film coated tabs	<i>HIV-1 infection</i> - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. <i>Hepatitis B infection</i> - for the treatment of chronic hepatitis B in adolescents aged 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.	Would not be commenced in NHS Borders – but prescription would continue if commenced at tertiary centre.	October 2013
905/13 Tenofovir disoproxil (as fumarate) 33mg/g oral granules	HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate. Hepatitis B infection - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.	Would not be commenced in NHS Borders – but prescription would continue if commenced at tertiary centre.	October 2013

906/13 Bimatoprost 0.3mg/ml plus timolol 5mg/ml preservative free single dose eye drops	For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.	Included in NHS Borders formulary for the SMC approved indication	October 2013
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – 9th September 2013</i>			
897/13 Pertuzumab 30mg/ml concentrate for sol for infusion	For use in combination with trastuzumab and docetaxel in adult patients with human epidermal growth factor-2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. Addition of pertuzumab to current first-line treatment (trastuzumab plus docetaxel) significantly increased progression-free and overall survival for women with HER2-positive metastatic breast cancer. The submitting company did not present a sufficiently robust economic analysis and in addition its justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	Not recommended for use in NHS Borders - not recommended by SMC	October 2013
915/13 Eculizumab 300mg concentrate for sol for infusion	In children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions.	Not recommended for use in NHS Borders - not recommended by SMC	October 2013
923/13 Imatinib 10mg/400mg film coated tabs	For the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.	Not recommended for use in NHS Borders - not recommended by SMC	October 2013
924/13 Vismodegib (Erivedge) 150mg hard caps	For the treatment of adult patients with: <ul style="list-style-type: none"> • symptomatic metastatic basal cell carcinoma • locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy 	Not recommended for use in NHS Borders - not recommended by SMC	October 2013

SCOTTISH MEDICINE CONSORTIUM RECOMMENDATIONS:

SMC ACCEPTED MEDICINE

Recommended for use within NHS Scotland – Embargoed Until 12th August 2013

	Indication	Formulary Decision & Rationale for non-inclusion	Date
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889/13 Ursodeoxycholic acid 500mg film-coated tablets	For the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on x-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s).	Included in NHS Borders formulary for the SMC approved indication	August 2013
890/13 Calcium polystyrene sulphonate powder for oral/rectal suspension	For the treatment of hyperkalaemia in patients with acute and chronic renal insufficiency including patients undergoing dialysis treatment.	Included in NHS Borders formulary for the SMC approved indication	August 2013
888/13 Abatacept 125mg/ml solution for subcutaneous injection in pre-filled syringe	In combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease modifying anti-rheumatic drugs including methotrexate or a TNF-Alpha inhibitor.	Included in NHS Borders formulary for the SMC approved indication	August 2013
887/13 Elvitegravir 150mg cobicistat 150mg emtricitabine 200mg tenofovir disoproxil (as fumarate) 245mg film coated tablet	Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are affected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	August 2013
835/13 Pirfenidone 267mg capsule	In adults for the treatment of mild to moderate idiopathic pulmonary fibrosis.	Included in NHS Borders formulary for the SMC approved indication	August 2013
812/12 Argatroban 100mg/ml concentrate for solution for infusion	Anticoagulation in adult patients with heparin-induced thrombocytopenia type 11 who require parenteral antithrombotic therapy.	Included in NHS Borders formulary for the SMC approved indication	August 2013
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
<i>Recommended for Restricted use within NHS Scotland – Embargoed Until 12th August 2013</i>			
835/13 Pirfenidone 267mg capsule	In adults for treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).	Duplicate item – see above	August 2013
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – 8th July 2013</i>			
878/13 Aflibercept 25mg/ml	In combination with irinotecan/5-fluorouracil/foloinic acid (FLOFIRI) chemotherapy aflibercept is indicated in adults with metastatic colorectal	Not recommended for use in NHS Borders - not	August 2013

concentrate for solution for infusion	cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.	recommended by SMC	
885/13 Chloroprocaine hydrochloride 10mg/ml solution for injection	Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes	Not recommended for use in NHS Borders - not recommended by SMC	August 2013
SMC ACCEPTED MEDICINE			
<i>Recommended for use within NHS Scotland – Embargoed Until 8th April 2013</i>			
	Indication	Formulary Decision & Rationale for non-inclusion	Date
857/13 Aflibercept 40mg/ml solution for intravitreal injection	In adults for the treatment of neovascular (wet) age-related macular degeneration.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	June 2013
<i>Recommended for use within NHS Scotland – Embargoed Until 13th May 2013</i>			
732/11 Ranibizumab 10mg/ml solution for injection	For the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO) in adults.	Included in NHS Borders formulary for the SMC approved indication	June 2013
862/13 Mirabegron 25mg & 50mg prolonged-release tablets	For symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.	Included in NHS Borders formulary for the SMC approved indication	June 2013
863/13 Lisdexamfetamine dimesylate 30mg, 50mg & 70mg caps	As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate.	Included in NHS Borders formulary for the SMC approved indication	June 2013
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
<i>Recommended for Restricted use within NHS Scotland – Embargoed 8th April 2013</i>			
719/11 Abatacept 250mg powder for concentrate for solution for infusion	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	June 2013
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – Embargoed 8th April 2013</i>			
855/13 Axitinib 1mg & 5mg film-	For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.	Not recommended for use in NHS Borders - not	June 2013

coated tablets		recommended by SMC	
865/13 Crizotinib 200mg & 250mg hard caps	For the treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Not recommended for use in NHS Borders - not recommended by SMC	June 2013
873/13 Abiraterone 250mg tabs	Abiraterone is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Not recommended for use in NHS Borders - not recommended by SMC	June 2013
874/13 Vildagliptin/metformin hydrochloride 50mg/850mg and 50mg/1000 mg film coated tablets	For the treatment of type 2 diabetes mellitus.	Not recommended for use in NHS Borders - not recommended by SMC	June 2013
875/13 Vildagliptin 50mg tabs	For the treatment of type 2 diabetes mellitus in adults.	Not recommended for use in NHS Borders - not recommended by SMC	June 2013
876/13 Rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride film coated tabs	For the initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines	Not recommended for use in NHS Borders - not recommended by SMC	June 2013
877/13 Tafamidis meglumine 20mg soft caps	For the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment.	Not recommended for use in NHS Borders - not recommended by SMC	June 2013

SCOTTISH MEDICINE CONSORTIUM RECOMMENDATIONS:

SMC ACCEPTED MEDICINE

Recommended for use within NHS Scotland – Embargoed Until 11th March 2013

	Indication	Formulary Decision & Rationale for non-inclusion	Date
851/13 Ingenol Mebutate 150 & 500micrograms	<p>Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.</p> <p>In four randomised, double-blind, phase III studies, a significantly greater proportion of adults with actinic keratosis (AK) achieved complete clearance when treated with ingenol mebutate gel compared with vehicle control.</p>	Included in NHS Borders formulary for the SMC approved indication	April 2013

<p>852/13 Rivaroxaban 15mg & 20mg film coated tablets</p>	<p>Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults.</p> <p>Rivaroxaban was non-inferior to a regimen including a low molecular weight heparin and a vitamin K antagonist for the treatment of PE and the prevention of recurrence of DVT or PE. Duration of treatment was 3, 6 or 12 months at the discretion of the treating physician.</p> <p>Experience with rivaroxaban in this indication for more than 12 months is limited therefore the cost-effectiveness of indefinite treatment has not been demonstrated</p>	<p>Included in NHS Borders formulary for the SMC approved indication</p>	<p>April 2013</p>
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Recommended for use within NHS Scotland – Embargoed Until 8th April 2013

<p>779/12 Ipilimumab 5mg/ml concentrate for infusion</p>	<p>Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.</p> <p>Ipilimumab demonstrated a survival benefit over an investigational glycoprotein100 peptide vaccine in previously treated patients with advanced melanoma.</p> <p>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ipilimumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.</p>	<p>Would be prescribed under SCAN regime</p>	<p>April 2013</p>
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<p>857/13 Aflibercept 40mg/ml solution for intravitreal injection</p>	<p>In adults for the treatment of neovascular (wet) age-related macular degeneration.</p> <p>In two pivotal randomised controlled studies the non-inferiority of aflibercept versus monthly injections of another anti-VEGF treatment was demonstrated for the primary endpoint; proportion of patients who maintained vision at week 52.</p> <p>The economic analysis submitted by the company related to the use of aflibercept in patients with wet AMD who have not previously been treated with anti-VEGF therapy</p>	<p>Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion</p>	<p>April 2013</p>
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SMC RECOMMENDED MEDICINES FOR RESTRICTED USE

Recommended for Restricted use within NHS Scotland – Embargoed Until 8th April 2013

<p>860/13 Insulin Glargine 100units/ml solution for</p>	<p>Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.</p> <p>SMC restriction: patients in whom treatment with an insulin analogue is</p>	<p>Included in NHS Borders formulary for the SMC approved indication</p>	<p>April 2013</p>
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injection in vial cartridge pre filled pen.	<p>appropriate.</p> <p>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.</p> <p>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.</p> <p>The pre-filled pen has previously been accepted for restricted use in patients from the age of 6 years and above.</p>		
861/13 Darunavir Oral Suspension 100mg/ml	<p>Co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight.</p> <p>SMC restriction: to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV.</p> <p>Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor.</p>	Would not be initiated in NHS Borders – but continued prescribing would be approved in NHS Borders	April 2013
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – Embargoed Until 8th April 2013</i>			
692/11 Botulinum Toxin Type A 50 unit, 100 unit & 200 unit powder for solution	<p>The prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).</p> <p>In pooled analysis of the two pivotal phase III studies, botulinum toxin type A significantly reduced the frequency of headache days compared with placebo.</p>	Not recommended for use in NHS Borders - not recommended by SMC	April 2013

	The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.		
855/13 Axitinib 1mg & 5mg film-coated tablets	<p>For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.</p> <p>In a phase III, open-label study, axitinib improved progression-free survival significantly more than another targeted therapy when used after first-line sunitinib or a cytokine. There was no significant improvement in overall survival.</p> <p>The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance, and in addition the submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.</p>	Not recommended for use in NHS Borders - not recommended by SMC	April 2013
856/13 Insulin Degludec 100units/ml solution for injection in pre filled pen or cartridge & 200 units/ml solution for injection in pre-filled pen	<p>For the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. SMC restriction: patients in whom treatment with an insulin analogue is appropriate.</p> <p>Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections. The pre-filled pen has previously been accepted for restricted use in patients from the age of 6 years and above.</p>	Not recommended for use in NHS Borders - not recommended by SMC	April 2013
866/13 Deferasirox	<p>For the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.</p> <p>The holder of the 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.</p>	Not recommended for use in NHS Borders - not recommended by SMC	April 2013

SMC ACCEPTED MEDICINE

Recommended for use within NHS Scotland – Embargoed Until 11th February 2013

	Indication	Formulary Decision &	Date
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		Rationale for non-inclusion	
840/13 colecalfiferol 800 international units (equivalent to 20 micrograms vitamin D ₃) tablets (Desunin 800 IU®)	For the prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered. The therapeutic use and safety profile of colecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. There are no comparative data for colecalciferol (Desunin®). It is the same cost as another vitamin D preparation	Included in NHS Borders formulary for the SMC approved indication	February 2013
838/13 palonosetron 500microgram soft capsules (Aloxi®)	For the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults. At recommended licensed doses the soft capsule formulation has been shown to be clinically non-inferior to the intravenous formulation and is cost neutral. SMC has previously accepted palonosetron intravenous injection for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.	Would be prescribed under SCAN regime	February 2013
836/13 <u>apixaban 2.5mg and 5mg film-coated tablets</u> (Eliquis®)	for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II). Apixaban was superior to standard oral anticoagulation at preventing stroke or systemic embolism in one large, double-blind study in patients with atrial fibrillation and at least one risk factor for stroke. It was also associated with a significant reduction in risk of major bleeding.	Included in NHS Borders formulary for the SMC approved indication	February 2013
834/13 <u>ulipristal acetate, 5mg, tablet (Esmya®)</u>	Pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months. Ulipristal was superior to placebo and non-inferior to a gonadotrophin releasing hormone (GnRH) agonist for reducing uterine bleeding in pre-operative women with uterine fibroids and excessive bleeding.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	February 2013
829/12 glycopyrronium 44 micrograms hard capsules	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Included in NHS Borders formulary for the SMC	February 2013

of inhalation powder (Seebri Breezhaler®)	In two phase III studies, glycopyrronium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [FEV ₁]) after 12 weeks.	approved indication	
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
<i>Recommended for Restricted use within NHS Scotland – Embargoed Until 11th February 2013</i>			
833/13 <u>ferumoxytol, 30mg/mL solution for injection (Rienso®)</u>	For the treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used. In two phase III studies the mean increase from baseline in haemoglobin was significantly higher for ferumoxytol than oral iron in non-haemodialysis dependent patients with chronic kidney disease. A mixed treatment comparison demonstrated equivalent efficacy outcomes for ferumoxytol versus a range of intravenous iron preparations.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	February 2013
841/13 linagliptin 2.5mg plus metformin 850mg and linagliptin 2.5mg plus metformin 1000mg film-coated tablets (Jentaduetto®)	Treatment of adult patients with type 2 diabetes mellitus: as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin; in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	February 2013
842/13 etanercept 10mg and 25mg powder and solvent for solution for injection for paediatric use, 25mg and 50mg solution for injection in pre-filled syringe, 50mg solution for injection in pre-filled pen (Enbrel®)	For the treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.	Would not be commenced in NHS Borders, but treatment would be continued if commenced at tertiary centre	February 2013
850/13 <u>linagliptin, 5mg film-coated tablets (Trajenta®)</u>	The treatment of type 2 diabetes mellitus to improve glycaemic control in adults:	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	February 2013

353/07 clostridium botulinum type A toxin- haemagglutinin complex 300 units and 500 units (Dysport®)	For focal spasticity of the upper limbs associated with stroke. Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) produces a localised reduction in muscle tone in patients with post-stroke upper limb spasticity and can improve patient disability at 16 weeks. It continues to be effective after repeated administrations with no new adverse events apparent.	Included in NHS Borders formulary for the SMC approved indication	February 2013
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – Embargoed Until 11th February 2013</i>			
837/13 mannitol, 400mg, inhalation powder, hard capsule (Bronchitol®)	Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. In two phase III clinical studies in patients with CF, inhaled mannitol was superior to a control treatment (a sub-therapeutic dose of inhaled mannitol) measured by absolute change in forced expiratory volume in one second (FEV ₁) over 26 weeks.	Not recommended for use in NHS Borders - not recommended by SMC	February 2013
SMC ACCEPTED MEDICINE			
<i>Recommended for use within NHS Scotland – Embargoed Until 10th December 2012</i>			
	Indication	Formulary Decision & Rationale for non-inclusion	Date
811/12 5-aminolaevulinic acid (as hydrochloride) 78mg/g, gel	Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).	Would not currently be used in NHS Borders as NHS Borders do not have PDT	November 2012
822/12 Bortezomib (Velcade®) 3.5mg powder for subcutaneous injection	In combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.	Would be prescribed under SCAN regime	November
823/12 Olmesartan medoxomil/amlodipine besilate/hydrochlorothiazide	In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.	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	November
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
<i>Recommended for Restricted use within NHS Scotland – Embargoed Until 10th December 2012</i>			

711/11 Ranibizumab, 10mg/ml solution for injectin	Treatment of visual impairment due to diabetic macular oedema (DMO) in adults.	Included in NHS Borders formulary for the SMC approved indication	November
809/12 Sildenafil (as citrate) 20mg film-coated tablets and 10mg/ml powder for oral solution	Treatment of paediatric patients aged 1 year to 17 year sold with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.	Treatment would not be initiated in NHS Borders, but if initiated at specialist centre NHS Borders would support use	November
819/12 Perampanel 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film coated tablets	Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.	Included in NHS Borders formulary for the SMC approved indication	November
821/12 Lanthanum carbonate 750mg & 100mg oral powder	As a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).	Included in NHS Borders formulary for the SMC approved indication	November
SMC MEDICINES NOT RECOMMENDED			
<i>Is not Recommended for Use within NHS Scotland – Embargoed Until 12th November 2012</i>			
824/12 Adalimumab	Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant: or who are intolerant to or have medical contraindications for such therapies.	Not recommended for use in NHS Borders - not recommended by SMC	November
820/12 Pazopanib 200mg, 400mg film-coated tablets	For the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. Efficacy and safety has only been established in certain STS histological tumour subtypes.	Not recommended for use in NHS Borders - not recommended by SMC	November
832/12 Racecadotril 100mg caps	Symptomatic treatment of acute diarrhoea in adults when casual treatment is not possible.	Not recommended for use in NHS Borders - not recommended by SMC	November
SMC ACCEPTED MEDICINE			
SMC Accepted Medicine	Indication	Formulary Decision & Rationale for non-	Date

		inclusion	
681/11 Velaglucerase alfa 400 units powder for solution for infusion	Long-term enzyme replacement therapy in patients with type 1 Gaucher disease.	Treatment would not be initiated in NHS Borders, but if initiated at specialist centre NHS Borders would support use	October 2012
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
763/12 Fingolimod (as hydrochloride)	<p>As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups:</p> <ul style="list-style-type: none"> • Patients with high disease activity despite treatment with a beta-interferon. <p>These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least one relapse in the previous year while on therapy, and have at least nine T2-hyperintense lesions in cranial magnetic resonance imaging (MRI) or at least one gadolinium-enhancing lesion.</p> <p>A “non-responder” could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.</p> <p>or</p> <p>Patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI</p>	Included in NHS Borders formulary for the SMC approved indication	October
774/12 Tocilizumab, 20mg/ml, concentrate for solution for infusion	Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.	Included in NHS Borders formulary for the SMC approved indication	October
802/12 Tegafur/gimeracil/oteracil 15mg/4.35mg/11.8mg & 20mg/5.8mg/15.8mg hard	tegafur/gimeracil/oteracil is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.	Not Included in NHS Borders formulary because clinicians do not support the	October

capsules		formulary inclusion	
SMC MEDICINES NOT RECOMMENDED			
792/12 Vemurafenib 240mg film coated tablet	<p>As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.</p> <p>A phase III, open-label study has demonstrated a significant improvement for the co-primary endpoints of overall survival and progression free survival for vemurafenib relative to an intravenous single agent chemotherapy regimen, in patients with previously untreated unresectable stage IIIC or stage IV melanoma with V600E BRAF mutation.</p> <p>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.</p>	Not recommended for use in NHS Borders - not recommended by SMC	October
SMC ACCEPTED MEDICINE			
793/12 Eplerenone 25, 50mg film-coated tablets	In addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic heart failure and left ventricular systolic dysfunction (LVEF≤30%).	Included in NHS Borders formulary for the SMC approved indication	August 2012
794/12 Pegylated interferon alfa-2b 50, 80, 100, 120 or 150 micrograms powder for solution for injection in pre-filled pen	In a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA.	Would not be initiated in NHS Borders, but treatment would be continued if commenced in tertiary centre.	August
798/12 Mercaptopurine 20mg/ml oral suspension	For the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children.	Included in NHS Borders formulary for the SMC approved indication	August
SMC RECOMMENDED MEDICINES FOR RESTRICTED USE			
652/10 Dexamethasone 700 microgram intravitreal implant	Treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion.	Not Included in NHS Borders formulary because clinicians do not support the formulary inclusion	August
674/11	Alone or in combination with methotrexate, for the treatment of active	Not Included in NHS	August

Golimumab, 50mg solution for injection in pre-filled pen	and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.	Borders formulary because clinicians do not support the formulary inclusion	
710/11 Tadalafil 20mg tablets	Treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II and III, to improve exercise capacity.	Would not be initiated in NHS Borders, but treatment would be continued if commenced in tertiary centre.	August
791/12 Fidaxomicin 200mg film-coated tablets	Treatment of adults with <i>Clostridium difficile</i> infections (CDI) also known as <i>C. difficile</i> -associated diarrhoea (CDAD).	Included in NHS Borders formulary for the SMC approved indication	August
795/12 Rufinamide 40mg/ml oral suspension	Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older.	Included in NHS Borders formulary for the SMC approved indication	August
764/12 Abiraterone acetate 250mg tablets	abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen.	Would be prescribed under SCAN regime	August
SMC MEDICINES NOT RECOMMENDED			
786/12 Belatacept powder for concentrate for solution for infusion 250mg vial and disposable syringe	Belatacept, in combination with corticosteroids and a mycophenolic acid, is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin-2 receptor antagonist for induction therapy to this belatacept-based regimen.	Not recommended for use in NHS Borders - not recommended by SMC	August
790/12 Thiotepa 15mg and 100mg powder for concentrate for solution for infusion	In combination with other chemotherapy medicinal products: 1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients; 2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.	Not recommended for use in NHS Borders - not recommended by SMC	August
800/12 Adalimumab pre-filled pen, pre-filled syringe	For the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine	Not recommended for use in NHS Borders - not recommended by	August

and vial	(AZA), or who are intolerant to or have medical contraindications for such therapies.	SMC	
803/12 Azilsartan medoxomil 20mg. 40mg & 80mg tablets	For the treatment of essential hypertension in adults.	Not recommended for use in NHS Borders - not recommended by SMC	August
804/12 Azithromycin dehydrate 15mg/g, eye drops, solution in single-dose container	Local antibacterial treatment of conjunctivitis caused by susceptible strains:	Not recommended for use in NHS Borders - not recommended by SMC	August
660/10 Amifampridine 10mg tablet as phosphate	Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.	Not recommended for use in NHS Borders - not recommended by SMC	August
SMC Accepted Medicine			
777/12 everolimus 5mg, 10mg tablets	Treatment of unresectable or metastatic, well or moderately differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease.	Would be prescribed under SCAN regime	June 2012
SMC not Recommended			
778/12 bevacizumab 25mg/ml concentrate for solution for infusion	Bevacizumab in combination with capecitabine is indicated for first-line treatment of patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate	Not recommended for use in NHS Borders - not recommended by SMC	June
779/12 ipilimumab 5mg/ml concentrate for solution for infusion	Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.	Not recommended for use in NHS Borders - not recommended by SMC	June
789/12 biogen idec ltd	Improvement of walking in adult patients with multiple sclerosis with walking disability.	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
- **Would be prescribed 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;
- **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**