

FORMULARY DECISIONS ON SMC ADVICE PUBLISHED UP TO DECEMBER 2015

(updated 08/06/2023)

To see decisions based on SMC advice published **from** January 2016, please [click here](#).

This update includes the decisions of the Formulary Subgroup of NHS Highland Area Drug and Therapeutics Committee (ADTC) regarding the Highland Formulary¹ status of new medicines, indications and formulations based on Scottish Medicines Consortium (SMC) advice² **published up to December 2015** and submissions and feedback from NHS Highland clinicians. Decisions are made in accordance with NHS Highland policy on dealing with SMC advice³. The Highland Formulary is not intended to be completely comprehensive, but gives guidance to prescribers especially on the use of standard first line agents for initial treatment. For information on the prescribing of non-Formulary medicines refer to relevant NHS Highland policies.⁴

Decisions made on the most recent SMC advice are based on the following nationally specified decision categories:

- Included in the Highland Formulary for the indication in question
- Not included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary
- Not included in the Highland Formulary because clinicians do not support formulary inclusion
- Not included in the Highland Formulary because clinicians have not responded to an invitation to apply for formulary inclusion to this medicine.
- Not included pending protocol.

To keep the tables as manageable as possible, the indications are given in brief. For full details, consult the full Summary of Product Characteristics⁵ or follow the link to the full SMC advice (blue underlined text).

For decisions based on SMC advice published **from** January 2016, please [click here](#).

1. Highland Formulary 6th edition available at <http://www.nhshighland.scot.nhs.uk/Publications/Documents/Guidelines/Formulary/Highland%20Formulary.pdf>
2. Scottish Medicines Consortium advice available at www.scottishmedicines.org
3. 'NHS Highland policy for acting on advice from the Scottish Medicines Consortium' (available at www.nhshighland.scot.nhs.uk)
4. 'Processes for the managed entry and use of medicines in NHS Highland' available at www.nhshighland.scot.nhs.uk)
5. Summaries of Product Characteristics may be available at www.emc.medicines.org.uk.

Formulary Subgroup of NHS Highland ADTC: Cumulative list of decisions on medicines/indications/formulations in response to more recent SMC advice published up to December 2015. If the SMC advice/medicine you are looking for is not listed, please see the medicines included in the current [Highland Formulary](#) e-document.

To see decisions based on SMC advice published **from** January 2016, please [click here](#).

SMC reference and status	Medicine	Indication	Date of publication on NHS Highland website	Highland Formulary status
811/12 Accepted	5-aminolaevulinic acid (as hydrochloride) (Ameluz®)	For the treatment of actinic keratosis of mild to moderate intensity on the face and scalp	29/01/2013	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
888/13 Accepted	Abatacept 125mg/mL solution for subcutaneous	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in	17/09/13 & 26/11/13	FS 24/03/15: Included in the Highland Formulary for this indication.

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	injection in a pre-filled syringe (Orencia®)	adult patients.		
719/11 Restricted with PAS	Abatacept 250mg powder for concentrate for solution for infusion (Orencia®)	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 tumour necrosis factor (TNF)-alpha inhibitor.	27/09/11 & 28/05/13 & 26/11/13	FS 24/03/15: Included in the Highland Formulary for this indication.
873/13 Accepted	Abiraterone acetate, 250mg tablets (Zytiga®)	With prednisone or prednisolone for treatment of metastatic castration resistant prostate cancer in adult men.	28/05/13 & 12/02/15 & 27/10/15	FS 27/10/15: Include in Highland Formulary for this indication.
810/12 Accepted	Acclidinium inhaler 322 micrograms (Eklira® Genuair)	Treatment of COPD	29/01/13 & 26/08/14	FS 26/08/14: Included in the Highland Formulary for this indication.
1034/15 Accepted	Acclidinium/formoterol fumarate dihydrate 340/12 micrograms inhalation powder (Duaklir Genuair®)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	14/04/15 & 24/03/15 & 24/05/16	FS 24/05/16: Included in the Highland Formulary for this indication.
1050/15 Restricted	Adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®)	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.	12/05/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
1068/15 Accepted restricted	Adalimumab 40 mg/0.8mL solution injection (Humira®)	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.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine: Include in the Highland Formulary for this indication.
880/13 Accepted restricted	Adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®)	Indicated for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age).	17/09/13	Included in Highland Formulary for this indication for 40mg solution for injection in a single-use pre-filled syringe and pre-filled pen. The 40mg/0.8mL paediatric vial is not included in Highland Formulary.
881/13 Accepted restricted	Adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®)	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	17/09/13	Included in Highland Formulary for this indication for 40mg solution for injection in a single-use pre-filled syringe and pre-filled pen. The 40mg/0.8mL paediatric vial is not

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		(DMARDs).		included in Highland Formulary.
858/13 Accepted	Adalimumab, 40mg/0.8mL, solution for injection (Humira®)	Treatment of adults with severe axial spondyloarthritis.	28/05/13	Included in Highland Formulary for this indication.
682/14 Accepted restricted use with PAS	Adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®)	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present.	08/04/14 & 30/10/14	FS 28/10/14: Included in the Highland Formulary for this indication.
920/14 Accepted	Afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®)	Monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s).	25/03/14	FS 25/03/14: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1074/15 Accepted with PAS	Aflibercept 40mg/mL solution for injection (Eylea®)	For adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.	08/09/15	FS 25/08/15: Formulary medicine: include in Formulary for this new indication
878/13 Accepted with PAS	Aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®)	In combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.	17/09/13 & 25/03/14 & 30/10/14	FS 28/10/14: Included in the Highland Formulary for this indication.
857/13 Accepted	Aflibercept 40mg/mL solution for intravitreal injection (Eylea®)	In adults for the treatment of neovascular (wet) age-related macular degeneration.	28/05/13	Included in Highland Formulary for this indication.
1003/14 Accepted restricted	Aflibercept, 40mg/mL solution for injection (Eylea®)	For adults for the treatment of visual impairment due to diabetic macular oedema (DMO).	13/11/14 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
954/14 Accepted with PAS	Aflibercept, 40mg/mL solution for injection (Eylea®)	For adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.	08/04/14	FS 25/03/14: Included in Highland Formulary for this indication.
959/14	Alemtuzumab (Lemtrada®)	Treatment of relapsing remitting multiple sclerosis	7/07/14 & 26/08/14	FS 26/08/14: Included in the Highland Formulary for this indication.
998/14 Restricted	Alogliptin 12.5mg plus metformin 1000mg combination tablet (Vipdomet®)	Treatment of adult patients aged 18 years and older with type 2 diabetes mellitus.	25/03/14 & 15/10/14 & 30/10/14	FS 28/10/14: Not included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary.
937/14	Alogliptin, 25mg,	For adults aged 18 years and older	15/10/14 &	FS 26/08/14: Not

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Accepted restricted (resubmission)	12.5mg, 6-25mg, film-coated tablets (Vipidia®)	with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin.	30/10/14	included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary
1115/15 Not recommended	Anakinra 100mg solution for injection in a pre-filled syringe (Kineret®)	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.	9/12/15 & 26/01/16	FS 26/01/16: Not included in Highland Formulary because not accepted by SMC.
836/13 Accepted	Apixaban tablets 2.5mg, 5mg (Eliquis®)	Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.	26/03/13 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
1029/15 Accepted	Apixaban, 2.5mg & 5mg, film-coated tablets (Eliquis®)	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults.	09/03/15 & 26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
1052/15 Accepted	Apremilast 10mg, 20mg and 30mg film-coated tablets (Otezla)	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.	09/06/15	FS 26/05/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1053/15 Accepted restricted	Apremilast 10mg, 20mg, 30mg tablets (Otezla)	Alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis.	09/06/15 & 25/08/15	FS 25/08/15: Formulary medicine: Include in the Highland Formulary for this indication.
812/12 Accepted	Argatroban (Exembol®)	For anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.	17/09/13	Included in Highland Formulary for this indication.
962/14 Accepted	Aripiprazole 400mg powder and solvent for prolonged release suspension for injection (Abilify Maintena®)	Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.	16/05/14 & 24/06/14	FS 24/06/14: Included in Highland Formulary for this indication.
891/13 Restricted	Aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®)	Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older.	17/09/13	Included in Highland Formulary for this indication.
1098/15 Accepted	Atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®)	In combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to	10/11/15	Not included in Highland Formulary because clinicians do not support Formulary inclusion.

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		atazanavir.		
909/13 Accepted	Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®)	Treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme.	26/11/13	Not Included in the Highland Formulary because clinicians do not support formulary inclusion.
1107/15 Restricted	Atomoxetine oral solution 4mg/mL (Strattera®)	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.	9/12/15 & 26/01/16	FS 26/01/16: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
980/14 Not recommended	Avanafil 50mg, 100mg and 200mg tablets (Spedra®)	Treatment of erectile dysfunction in adult men.	24/06/14	FS 24/06/14: Not included in Highland Formulary because not accepted by SMC.
980/14 Not recommended	Avanafil 50mg, 100mg, 200mg tablets (Spedra®)	Treatment of erectile dysfunction (ED) in adult men.	08/09/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
855/13 Accepted with PAS	Axitinib (Inlyta®)	Treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.	28/05/13 & 26/11/13 & 24/06/14	FS 24/06/14: Included in Highland Formulary for this indication
921/14 Accepted	Azelastine hydrochloride 137 micrograms plus fluticasone propionate 50 micrograms per actuation nasal spray (Dymista®)	Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	28/01/14 & 15/10/14 & 30/10/14 & 30/01/15	FS 24/06/14: Included in Highland Formulary for this indication.
950/14 Accepted	Azithromycin 500mg powder for solution for infusion (Zedbac®)	Treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required.	08/04/14	FS 25/03/14: Not included in Highland Formulary for this indication because clinicians do not support formulary inclusion.
753/12 Restricted Resubmission	Aztreonam lysine 75mg powder and solvent for nebuliser solution (Cayston®)	Suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older.	13/01/15 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support formulary inclusion.
976/14 Accepted	Beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100 micrograms/6 micrograms	Symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	07/07/14	FS 24/06/14: Included in Highland Formulary for this indication.

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	(Fostair®)			
1063/15 Accepted Restricted with PAS. (PACE)	Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®)	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.	08/09/15 & 27/10/15	FS 25/08/15: Include in Highland Formulary for this indication.
806/12 Restricted (Resubmission) (PACE)	Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®)	In combination with carboplatin and paclitaxel is indicated for the front- line treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer.	13/01/15 & 30/01/15 & 10/11/15 & 24/03/16	FS 22/03/16: Included in the Highland Formulary for this indication.
906/13 Restricted	Bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eye- drops (Ganfort®)	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.	21/10/13 & 26/11/13 & 30/10/14	FS 28/10/14: Included in the Highland Formulary for this indications.
312/06 , 839/13 , 07/02 Accepted	Bimatoprost eye drops/ Preservative-free eye drops, Bimatoprost and timolol eye drops/ Preservative-free eye drops	Reduction of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension	30/10/14	FS 28/10/14: Included in the Highland Formulary for this indication.
927/13 Restricted	Bortezomib 3-5mg powder for solution for injection (Velcade®)	In combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma.	28/01/14	Included in the Highland Formulary for this indication.
1075/15 Accepted	Bortezomib 3-5mg powder for solution for injection (Velcade®)	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.	08/09/15 & 27/10/15	FS 27/10/15: Include in Highland Formulary for this indication.
910/13 Accepted with PAS (resubmission)	Bosutinib 100mg, 500mg film-coated tablets (Bosulif®)	Treatment of adult patients with chronic phase, accelerated phase, and blast phase Philadelphia chromosome positive chronic myelogenous leukaemia.	26/11/13 & 12/02/15 & 25/08/15	FS 25/08/15: Formulary medicine: Include in the Highland Formulary for this indication.
986/14 Not recommended	Botulinum toxin type A 50, 100 and 200 units (Botox®)	Focal lower limb spasticity, including the treatment of ankle disability due to lower limb spasticity associated with stroke in adults.	07/07/14	FS 24/06/14: Not included in Highland Formulary because not accepted by SMC.
916/13 Accepted	Botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®)	Management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis.	21/10/13 & 26/11/13	Included in the Highland Formulary for this indication (the 200 unit vial is not included in the Formulary).
931/13	Botulinum toxin	Management of bladder	28/01/14 &	FS 24/06/14: Included in

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Restricted	type A powder for solution for injection (Botox®)	dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency.	07/07/14	Highland Formulary for this indication.
692/11 Not recommended	Botulinum toxin type A powder for solution for injection 50 unit, 100 unit, 200 unit	Prophylaxis of headaches in adults with chronic migraine.	28/05/13	Not included in Highland Formulary because not accepted by SMC.
845/12 Restricted	Brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®)	Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL).	15/10/14 & 30/10/14 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
1016/14 Restricted	Brimonidine, 3-3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®)	Symptomatic treatment of facial erythema of rosacea in adult patients.	13/01/15 & 30/01/15 & 24/01/17	FS 24/01/17: : Included in the Highland Formulary for this indication.
991/14 Accepted	Brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops, suspension (Simbrinza®)	Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	13/11/14	FS 28/10/14: Included in the Highland Formulary for this indication.
831/12 Recommended	budesonide 3mg gastro-resistant capsule (Budenofalk®)	SMC has accepted budesonide for the symptomatic relief of chronic diarrhoea due to collagenous colitis.	29/01/13	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
970/14 Accepted	Budesonide 9mg gastro-resistant granules (Budenofalk®)	Induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon.	24/06/14	FS 24/06/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
1093/15 Not recommended	Budesonide 9mg prolonged release tablets (Cortiment®)	In adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient.	27/10/15	FS 27/10/15: Not included in Highland Formulary because not accepted by SMC.
1043/15 Restricted	Budesonide, 3mg, gastro-resistant capsules (Budenofalk®)	Autoimmune hepatitis.	12/05/15 & 28/05/15	FS 26/05/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1022/15 Not recommended	Cabozantinib 20mg and 80mg hard capsules (Cometriq®)	Treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma.	09/03/15 & 26/03/15	FS 24/03/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
814/12 Accepted	Caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®)	Treatment of primary apnoea of premature newborns.	17/09/13	Not included in Highland Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this indication.
890/13	Calcium	Treatment of hyperkalaemia in	17/09/13	Not included in Highland

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Accepted	polystyrene sulphonate powder for oral/rectal suspension (Sorbisterit®)	patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment.		Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this indication.
1019/14 Restricted	Canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediate-release tablets (Vokanamet®)	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control.	13/01/15 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
963/14 Restricted	Canagliflozin, 100mg and 300mg film-coated tablets (Invokana®)	In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on therapy with other glucose-lowering medicinal products including insulin.	24/06/14	FS 24/06/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
882/13 Not recommended (non-submission)	Canakinumab (Ilaris®)	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS).	28/05/13 (reported 11/06/13)	Not included in Highland Formulary for this indication because not accepted by SMC.
883/13 Not recommended (non-submission)	Canakinumab (Ilaris®)	Symptomatic treatment of adult patients with frequent gouty arthritis attacks.	28/05/13 (reported 11/06/13)	Not included in Highland Formulary for this indication because not accepted by SMC.
926/13 Rejected Non-submission	Canakinumab 150mg powder for solution for injection (Ilaris®)	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.	26/11/13	Not included in Highland Formulary because not accepted by SMC.
1070/15 Rejected	Cangrelor (Kengrexal)	Co-administered with acetylsalicylic acid for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease.	09/06/15	FS 26/05/15: Not included in Highland Formulary because not accepted by SMC.
673/11 Accepted Restricted	Capsaicin 179mg cutaneous patch (Qutenza®)	Treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.	15/10/14 & 30/10/14 & 30/01/15 & 09/03/15 & 26/03/15	FS 26/03/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
899/13 Accepted	Carglumic acid 200mg dispersible tablets (Carbaglu®)	Hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.	21/10/13 & 26/11/13	Not Included in the Highland Formulary because clinicians do not support Formulary inclusion.
830/12 Recommended	ceftaroline fosamil (Zinforo®)	SMC accepted ceftaroline fosamil for restricted use in patients with known or suspected meticillin-resistant Staphylococcus aureus (MRSA) infection.	29/01/2013	Not included in Highland Formulary because clinicians do not support Formulary inclusion.

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943/14 Accepted restricted Resubmission	Ceftobiprole, 500mg, powder for concentrate for solution for infusion (Zevtera®)	Treatment of the following infections in adults: <ul style="list-style-type: none"> Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) Community-acquired pneumonia (CAP). 	22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
932/13 Not recommended	Cefuroxime sodium 50mg powder for solution for injection (Aprokam®)	Antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.	28/01/14 & 14/11/17	FS 14/11/17: Included in the Highland Formulary for this indication.
1097/15 Accepted	Ceritinib 150mg hard capsules (Zykadia®)	Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.	9/12/15 & 26/01/16 & 25/10/16	FS 25/10/16: Included in the Highland Formulary for this indication.
960/14 Accepted	Certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®)	Certolizumab pegol is indicated for the treatment of adult patients with severe active axial spondyloarthritis.	16/05/14 & 24/06/14 & 25/10/16	FS 25/10/16: Included in the Highland Formulary for this indication.
973/14 Restricted	Certolizumab pegol, 200mg/mL, solution for injection in pre-filled syringe (Cimzia®)	In combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.	07/07/14 & 25/10/16	FS 25/10/16: Included in the Highland Formulary for this indication.
590/09 superseded by NICE MTA 375	Certolizumab pegol, 200mg/mL, solution for injection in pre-filled syringe (Cimzia®)	Treatment of rheumatoid arthritis	25/10/16	FS 25/10/16: Included in the Highland Formulary for this indication.
1012/14 Accepted Restricted	Cetuximab, 100mg/20mL and 500mg/100mL solution for infusion (Erbix®)	Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer.	13/01/15 & 30/01/15 & 09/03/15 & 26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
885/13 Not recommended	Chloroprocaine hydrochloride, 10mg/mL, solution for injection (Ampres®)	Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes.	17/09/13	Not included in Highland Formulary because not accepted by SMC.
1089/15 Accepted	Ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®)	Treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.	27/10/15 & 24/05/16	FS 24/05/16: Included in the Highland Formulary for this indication.
1010/14 Accepted	Clindamycin 1%/tretinoin 0.025% gel (Treclin®)	Topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older.	10/12/14 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support formulary inclusion.

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353/07 Recommended	Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®)	SMC has accepted Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) for restricted use in the treatment of focal spasticity of the upper limbs associated with stroke.	29/01/13	Included in the Highland Formulary for this indication.
933/13 Not recommended	Cobicistat 150mg film-coated tablet (Tybost®)	Pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults.	16/05/14 & 24/06/14	FS 24/06/14: Not included in Highland Formulary because not accepted by SMC.
1011/14 Accepted	Colecalciferol 25,000 international units oral solution (InVita D3®)	Prevention and treatment of vitamin D deficiency.	10/12/14 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
939/14 Not recommended (resubmission)	Colestilan 1g film-coated tablet, 2g and 3g granules sachet (BindRen®)	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	25/03/14 & 11/08/14 & 26/08/14	FS 26/08/14: Not included in Highland Formulary because not accepted by SMC.
939/14 Not recommended	Colestilan 1g film-coated tablets, 2g and 3g granules sachets (BindRen®)	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	12/02/15	FS 27/01/15: Not included in Highland Formulary because not accepted by SMC (Independent Review Panel).
HIS / NICE MTA 276	Colistimethate sodium dry powder for inhalation	Treatment of chronic pulmonary infection caused by <i>Pseudomonas aeruginosa</i> in people with cystic fibrosis.	17/09/13	Included in Highland Formulary for this indication.
1059/15 Not recommended	Collagenase clostridium histolyticum (Xiapex®)	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.	12/05/15 & 28/05/15	FS 26/05/15: Not included in Highland Formulary because not accepted by SMC.
865/13 Accepted	Crizotinib (Xalkori®) hard capsule 200mg and 250mg	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	28/05/13 & 21/10/13 & 26/11/13 & 25/03/14	FS 25/03/14: Included in the Highland Formulary for this indication.
995/14 Accepted	Dabigatran etexilate, 110mg, 150mg capsules (Pradaxa®)	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	15/10/14 & 30/10/14	FS 28/10/14: Included in the Highland Formulary for this indication.
1023/15 Accepted Restricted	Dabrafenib, 50mg and 75mg hard capsules (Tafinlar®)	Monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.	09/03/15 & 26/03/15 & 27/10/15	FS 27/10/15: Include in Highland Formulary for this indication.
1002/14 Accepted restricted	Daclatasvir 30mg and 60mg film-coated tablets (Daklinza®)	In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults.	13/11/14	FS 28/10/14: Included in the Highland Formulary for this indication.
799/12 Restricted	Dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®)	For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy.	25/03/14 & 7/07/14	FS 24/06/14: Included in Highland Formulary for this indication.
983/14	Dapagliflozin plus	In adults aged 18 years and older	11/08/14 &	FS 26/08/14: Not

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Accepted restricted	metformin 5mg/850mg and 5mg/1000mg film-coated tablets (Xigduo®)	with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control.	26/08/14	included in the Highland Formulary because clinicians do not support Formulary inclusion.
987/14 Not recommended	Dapoxetine hydrochloride 30mg and 60mg film-coated tablets (Priligy®)	Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.	07/07/14	FS 24/06/14: Not included in Highland Formulary because not accepted by SMC.
948/14 Restricted	Darunavir 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®)	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 12 to 17 years of age.	25/03/14	FS 25/03/14: Not included in Highland Formulary for this indication because clinicians do not support formulary inclusion.
1069/15 Accepted restricted	Darunavir 75mg, 150mg, 400mg, 600mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®)	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 >100x10 ⁶ cells/L.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine (tablets 600mg, 800mg, oral suspension 100mg/ml) Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
1081/15 Accepted	Darunavir 800mg, cobicistat 150mg film-coated tablet (Rezolsta®)	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.	11/08/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
861/13 Restricted	Darunavir oral suspension 100mg/mL (Prezista®)	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.	28/05/13	Included in Highland Formulary for this indication.
866/13 Not recommended (non-submission)	Deferasirox 125mg, 250mg and 500mg dispersible tablets (Exjade®)	Treatment of chronic iron overload requiring chelation therapy.	28/05/13	Not included in Highland Formulary for this indication because not accepted by SMC (Already included in Highland Formulary for indication as specified in SMC 347/07).
967/14 Accepted	Defibrotide, 80mg/mL, concentrate for solution for infusion (Defitelio®)	Treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy.	24/06/14	FS 24/06/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
1119/15 Not	Denosumab 120mg solution for injection	Adults and skeletally mature adolescents with giant cell tumour	9/12/15 & 26/01/16	FS 26/01/16: Not included in Highland

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recommended	(Xgeva®)	of bone that is unresectable or where surgical resection is likely to result in severe morbidity.		Formulary because not accepted by SMC.
1013/14 Not recommended	Denosumab 60mg solution for injection in a pre-filled syringe (Prolia®)	Osteoporosis in men at increased risk of fractures.	13/11/14	FS 28/10/14: Formulary medicine: not included in Highland Formulary for this indication because not accepted by SMC.
652/10 Accepted with restrictions	dexamethasone (Ozurdex)	Treatment of adult patients with macular oedema following either branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).	12/06/12	Included in the Highland Formulary for this indication.
1046/15 Accepted	Dexamethasone 700 micrograms intravitreal implant in applicator (Ozurdex®)	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.	12/05/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
784/12 Accepted	Dexmedetomidine hydrochloride (Dexdor)	For sedation of adult ICU patients requiring a sedation level not deeper than arousal in response to verbal stimulation	14/08/12 & 28/03/17	FS 28/03/17: Included in Highland Formulary for this indication.
886/14 Accepted with PAS	Dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®)	Treatment of adult patients with relapsing remitting multiple sclerosis.	08/04/14 & 24/06/14	FS 24/06/14: Included in Highland Formulary for this indication
961/14 Accepted	Dolutegravir 50mg film-coated tablets (Tivicay®)	In combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age.	16/05/14 & 24/06/14	FS 24/06/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
1009/14 Accepted	Dolutegravir 50mg, abacavir 600mg plus lamivudine 300mg film-coated tablets (Triumeq®)	Treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40kg.	10/12/14 & 30/01/15 & 27/10/15	FS 27/10/15: Include in Highland Formulary for this indication.
915/13 Not recommended	Eculizumab 300 mg concentrate for solution for infusion (Soliris®)	In children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH).	17/09/13	Not included in Highland Formulary because not accepted by SMC.
1090/15 Accepted	Edoxaban tosilate 15mg, 30mg, 60mg film-coated tablets (Lixiana®)	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	10/11/15	FS 27/10/15 Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1095/15 Accepted	Edoxaban tosilate 15mg, 30mg and 60mg film-coated tablets (Lixiana®)	Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors.	10/11/15 & 14/11/17	FS 14/11/17: Included in the Highland Formulary for this indication.
1125/15 Accepted	Efavirenz 50mg, 100mg and 200mg hard capsules and 600mg film-coated tablets (Sustiva®)	Antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3-5kg.	9/12/15 & 26/01/16	FS 26/01/16: Formulary medicine. Included in the Highland Formulary for this indication.

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1072/15 Not recommended (PACE)	Elosulfase alfa, 1mg/mL concentrate for solution for infusion (Vimizim®)	Treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages.	08/09/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
919/13 Accepted	Eltrombopag, 25mg, 50mg, 75mg film-coated tablets (Revolade®)	In chronic hepatitis C virus infection, for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.	28/01/14	Included in the Highland Formulary for the indication in question.
971/14	Elvitegravir 85mg and 150 mg film-coated tablets (Vitekta®)	Co-administered with a ritonavir-boosted protease inhibitor and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults.	16/05/14 & 24/06/14	FS 24/06/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
887/13 Accepted with PAS	Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg film coated tablet (Stribild®)	(HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®.	17/09/13 & 26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
993/14 Restricted	Empagliflozin 10mg and 25mg tablet (Jardiance®)	Treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy.	15/10/14 & 30/10/14 & 26/01/16	FS 26/01/16 Include in Highland Formulary for this indication.
1092/15 Restricted	Empagliflozin plus metformin 5mg/85mg, 5mg/1000mg, 12.5mg/850mg, 12.5mg/1000mg film-coated tablets (Synjardy®)	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control.	27/10/15	FS 27/10/15 Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1049/15 Restricted	Entecavir 0.5 and 1mg film-coated tablets and 0.05mg/mL oral solution (Baraclude®)	Treatment of chronic hepatitis B virus infection in nucleoside naïve paediatric patients from 2 to <18 years of age with compensated liver disease.	12/05/15 & 28/05/15	FS 26/05/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1066/15 Accepted	Enzalutamide 40mg soft capsules (Xtandi®)	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.	11/08/15 & 25/08/15 & 24/03/16	FS 22/03/16: Included in the Highland Formulary for this indication
911/13 Accepted with PAS	Enzalutamide 40mg soft capsules (Xtandi®)	Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy.	26/11/13 & 25/03/14	FS 25/03/14: Included in the Highland Formulary for this indication.
749/11 Accepted	Erlotinib 25, 100 and 150mg film-coated tablets	First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)		Retrospectively added – assumed noted at FS 31/01/12: Not included in

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	(Tarceva®)	with epidermal growth factor receptor (EGFR) activating mutations.		Highland Formulary because clinicians do not support Formulary inclusion.
592/09 Accepted Restricted	Eslicarbazepine tablets 800mg (Zebinex)	Adjunctive therapy in adults with partial-onset seizures.	26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
901/13 Restricted	Etravirine 25mg, 100mg, 200mg tablets (Intelence®)	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.	17/09/13	Not included in Highland Formulary because clinicians do not support formulary inclusion.
777/12 Accepted	Everolimus (Afinator)	Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease.	12/06/12 & 24/05/16	FS 24/05/16: Included in the Highland Formulary for this indication.
884/13 Not recommended (non-submission)	Everolimus (Votubia®)	Treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex.	28/05/13 (reported 11/06/13)	Not included in Highland Formulary for this indication because not accepted by SMC.
1117/15 Not recommended	Everolimus 0.25mg, 0.5mg and 0.75mg tablets (Certican®)	Prophylaxis of organ rejection in patients at low to moderate immunological risk receiving a cardiac transplant; prophylaxis of organ rejection in patients receiving hepatic transplant.	27/10/15	Not included in Highland Formulary because not accepted by SMC.
595/10 Accepted Resubmission	Everolimus 5 and 10mg tablets (Afinitor®)	Treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.	13/11/14 & 30/01/15 & 26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
947/13 Not recommended	Fentanyl citrate 200 micrograms, 400 micrograms and 800 micrograms buccal film (Breakyl®)	Treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.	28/01/14	Not included in Highland Formulary because not accepted by SMC.
833/13 Recommended for restricted use	ferumoxytol (Rienso®)	SMC has accepted ferumoxytol for restricted use in the treatment of iron deficiency anaemia in nonhaemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used.	26/03/13	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
992/14 Accepted restricted (PAS)	Fingolimod 0.5mg hard capsules (Gilenya®)	As a single disease modifying therapy in highly active relapsing remitting multiple sclerosis.	15/10/14 & 30/10/14 & 30/01/15	FS 27/01/15: Formulary medicine. Included in the Highland Formulary for this indication.
1038/15 Accepted	Fingolimod 0.5mg hard capsules (Gilenya®)	Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS).	14/04/15	FS 24/03/15: Formulary medicine: Included in the Highland Formulary for this indication.
864/13	Fluocinolone	Treatment of vision impairment	28/05/13	Not included in Highland

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Not recommended	acetonide (Iluvien®)	associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.	(reported 11/06/13)	Formulary for this indication because not accepted by SMC.
864/13 Accepted restricted with PAS	Fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®)	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.	17/09/13 & 25/03/14	FS 25/03/14: Not included in Highland Formulary because clinicians do not support formulary inclusion.
953/14 Accepted restricted	Fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar Ellipta®)	Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	08/04/14	FS 25/03/14: Included in Highland Formulary for this indication.
966/14 Accepted	Fluticasone furoate/vilanterol 92/22, 184/22 micrograms inhalation powder (Relvar® Ellipta®)	Regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate.	24/06/14	FS 24/06/14: Included in Highland Formulary for this indication.
736/11 Accepted	Fluticasone propionate and formoterol fumarate metered dose inhaler, 50microgram/5 microgram, 125microgram/5 microgram 250microgram/10 microgram (Flutiform®)	Regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β 2 agonist (LABA)] is appropriate	27/11/12 & 26/03/13	Included in Highland Formulary for this indication.
1025/15 Accepted	Follitropin alfa 75 units, 150 units, 225 units, 300 units, 450 units pre-filled pen for subcutaneous injection (Bemfola®)	In adult women for anovulation (including polycystic ovarian syndrome); stimulation of multi-follicular development in women undergoing superovulation; with luteinising hormone (LH) preparation for stimulation of follicular development.	12/02/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support formulary inclusion.
1033/15 Accepted Restricted	Fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt®)	Treatment of infections in adults and children including neonates.	09/03/15 & 26/03/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
373/07 Accepted	Fostair metered dose inhaler	For the treatment of asthma	26/11/13	Included in Highland Formulary for this indication.
615/10 Restricted (Resubmission)	Gefitinib 250mg film-coated tablets (Iressa®)	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).	9/12/15 & 26/01/16	FS 26/01/16: Formulary medicine. Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1108/15	Glatiramer acetate	Treatment of relapsing forms of	09/12/15 &	FS 26/01/16: Formulary

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Accepted	40mg/mL solution for injection prefilled syringes (Copaxone®)	multiple sclerosis (MS).	26/01/16 & 26/01/16	medicine. Include this formulation in the Highland Formulary
829/12 Accepted	glycopyrronium inhalation powder (Seebri Breezhaler®)	For a once daily maintenance bronchodilator treatment to relieve symptoms in patients with COPD.	29/01/13	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
674/11 Accepted with restrictions	golimumab (Simponi®)	treatment of active and progressive psoriatic arthritis in adult patients when the response to at least two previous disease-modifying antirheumatic drugs (DMARDs) has been inadequate.	14/08/12	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
946/13 Not recommended	Golimumab, 50mg and 100mg solution for injection (Simponi®)	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy.	28/01/14 & 15/10/14 & 30/10/14	FS 26/08/14: Not included in Highland Formulary because not accepted by SMC.
895/13 Accepted	Granisetron 3.1mg / 24 hours transdermal patch (Sancuso®)	In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy.	21/10/13 & 26/11/13	Not Included in the Highland Formulary because clinicians do not support Formulary inclusion.
476/08 Accepted	icatibant (Firazyr)	For the treatment of symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (type I and II HAE).	27/03/12	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1026/15 Accepted Restricted	Idelalisib 100mg and 150mg tablets (Zydelig®)	In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL).	09/03/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
1039/15 Accepted	Idelalisib 100mg, 150mg tablets (Zydelig®)	Treatment of follicular lymphoma that is refractory to two prior lines of treatment	27/10/15	FS 27/10/15: Include in Highland Formulary for this indication.
1039/15 Accepted	Idelalisib, 100mg and 150mg film-coated tablets (Zydelig®)	Monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.	12/05/15 & 28/05/15	FS 26/05/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
426/07 Not recommended (Non-submission)	Imatinib (Glivec®)	Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia as monotherapy	26/11/13	Included in Highland Formulary for this indication.
923/13 Rejected Non-submission	Imatinib 100mg/400mg film coated tablets (Glivec®)	Treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.	21/10/13 & 26/11/13	Not included in Highland Formulary because not accepted by SMC.
934/13	Imiquimod 3.75%	Topical treatment of clinically	28/01/14	Not included in Highland

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Not recommended	cream (Zyclara®)	typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults.		Formulary because not accepted by SMC.
922/13 Accepted	Indacaterol maleate 143 micrograms plus glycopyrronium bromide 63 micrograms inhalation powder hard capsules (Ultibro® Breezhaler®)	Maintenance bronchodilator in COPD	10/12/14 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
374/07 Not recommended (Resubmission)	Infliximab 100mg solution for infusion (Remicade®)	Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy.	16/05/14 & 24/06/14	FS 24/06/14: Not included in Highland Formulary because not accepted by SMC.
1006/14 Restricted	Infliximab, 100mg, powder for concentrate for solution for infusion (Remsima®)	Rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function.	14/04/15	FS 24/03/15: Formulary medicine: Included in the Highland Formulary for this indication.
1007/14 Restricted	Infliximab, 100mg, powder for concentrate for solution for infusion (Inflectra®)	Rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function.	14/04/15	FS 24/03/15: Formulary medicine: Included in the Highland Formulary for this indication.
851/13 Accepted	ingenol mebutate gel (Picato)	Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.	26/03/13	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1060/15 Not recommended	Insulin degludec (Tresiba®)	Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year.	12/05/15 & 28/05/15	FS 26/05/15: Not included in Highland Formulary because not accepted by SMC.
1088/15 Restricted	Insulin degludec/liraglutide 100 units/mL/3-6mg/mL solution for injection pre-filled pen (Xultophy®)	Treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products.	27/10/15	FS 27/10/15 Not included in Highland Formulary because clinicians do not support Formulary inclusion.
860/13 Restricted	Insulin glargine 100units/ML solution for injection in a vial, cartridge, pre-filled pen (Lantus®, Clikstar®, Lantus®Solo-star®)	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.	28/05/13	Included in Highland Formulary for this indication.
1078/15 Restricted	Insulin glargine 300 units/mL solution for injection in a pre-filled pen (Toujeo®)	Treatment of type 1 or type 2 diabetes mellitus in adults aged 18 years and above.	08/09/15 & 23/08/16	FS 23/08/16: Included in Highland Formulary for this indication.

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779/12 Accepted with PAS	Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.	28/05/13 & 28/01/14	Included in Highland Formulary for this indication.
997/14 Accepted	Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use).	13/11/14 & 30/01/15	FS 27/01/15: Formulary medicine. Included in the Highland Formulary for this indication.
827/12 Not recommended	Ivacaftor (Kalydeco®)	Treatment of cystic fibrosis (CF) in patients age 6 years and older who have a <i>G551D</i> mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	29/01/13 & 28/05/13 (reported 11/06/13)	Not included in Highland Formulary for this indication because not accepted by SMC.
1104/15 Restricted	Ivermectin 10mg/g cream (Soolantra®)	Topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.	9/12/15 & 26/01/16 & 26/01/16 & 26/01/16	FS 26/01/16: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1100/15 Rejected (non-submission)	Ketoconazole 200mg tablets (Ketoconazole HRA®)	Treatment of endogenous Cushing's syndrome in adults and adolescents above the age of 12 years.	08/09/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
925/13 Not recommended Non-submission	Lapatinib 250mg film-coated tablets (Tyverb®)	Treatment of adult patients with breast cancer.	26/11/13	Not included in Highland Formulary because not accepted by SMC.
879/13 Accepted restricted	Latanoprost 50 microgram/mL preservative-free single-dose eye-drops (Monoprost®)	Reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. Restricted to use in patients who have proven sensitivity to the preservative benzalkonium chloride.	17/09/13	Included in Highland Formulary for this indication.
1030/15 Accepted Restricted	Ledipasvir/sofosbuvir, 90mg/400mg, film-coated tablet (Harvoni®)	Treatment of chronic hepatitis C (CHC) in adults.	09/03/15 & 26/03/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
1084/15 Restricted	Ledipasvir/sofosbuvir 90mg/400mg film-coated tablet (Harvoni®)	Treatment of genotype 3 chronic hepatitis C (CHC) in adults.	08/09/15	FS 25/08/15: Formulary medicine: include in Formulary for this new indication
441/08 Accepted restricted	Lenalidomide 5mg, 10mg, 15mg and 25mg capsules (Revlimid®)	In combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy.	08/04/14	FS 25/03/14: Included in Highland Formulary for this indication.
1096/15 Restricted	Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®)	Treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.	9/12/15 & 26/01/16	FS 26/01/16: Included in Highland Formulary for this indication.
942/14 Accepted	Lenalidomide 2.5mg, 5mg, and 10mg, hard	Treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk	25/03/14	FS 25/03/14: Included in the Highland Formulary for this indication.

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	capsules (Revlimid®)	myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.		
1036/15 Accepted	Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®)	Contraception for up to 3 years.	14/04/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
938/14 Accepted	Levonorgestrel 1500 microgram tablet (Upostelle®)	Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.	25/03/14	FS 25/03/14: Included in Highland Formulary for this indication.
1058/15 Accepted	Levonorgestrel 20 micrograms/24 hours intrauterine delivery system (Levosert)	Contraception. Heavy menstrual bleeding.	09/06/15 & 22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
869/13 Accepted Restricted	Linacotide (Constella®)	Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.	28/05/13 (reported 11/06/13)	Not included in Highland Formulary because clinicians do not support formulary inclusion.
1057/15 Restricted	Linagliptin 2.5mg plus metformin 850mg and linagliptin 2.5mg plus metformin 1000mg film-coated tablets (Jentadueto)	Treatment of adult patients with type 2 diabetes mellitus in combination with insulin.	09/06/15	FS 26/05/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
746/11 Restricted	Linagliptin, 5mg film-coated tablets (Trajenta®)	Treatment of type 2 diabetes mellitus to improve glycaemic control in adults in monotherapy or combination therapy.	26/03/13 & 28/05/13	Included in Highland Formulary for this indication.
850/13 Accepted (Resubmission)	Linagliptin, 5mg film-coated tablets (Trajenta®)	Treatment of type 2 diabetes mellitus to improve glycaemic control in adults in monotherapy or combination therapy.	12/05/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
908/14 Accepted restricted	Lipegfilgrastim 6mg, solution for injection (Lonquex®)	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy.	08/04/14	FS 25/03/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
1044/15 Accepted	Liraglutide 6mg/mL prefilled pen for injection (3mL) (Victoza®)	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.	12/05/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
863/13 Accepted	Lisdexamfetamine dimesylate, 30mg, 50mg & 70mg capsules	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.	28/05/13 & 26/11/13	Included in Highland Formulary for this indication.

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1079/15 Accepted	Lisdexamfetamine dimesylate, 30mg, 50mg and 70mg hard capsules (Elvanse Adult®)	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.	08/09/15	FS 25/08/15: Formulary medicine: include in Formulary for this new indication
903/13 Restricted	Lixisenatide 10microgram/0.2mL, 20microgram/0.2mL solution for injection in pre-filled disposable pen (Lyxumia®)	Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin.	17/09/13	Not included in Highland Formulary because clinicians do not support formulary inclusion.
956/14 Not recommended	Lomitapide 5mg, 10mg, 20mg hard capsules (Lojuxta®)	Adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis in adult patients with homozygous familial hypercholesterolaemia (HoFH).	25/03/14	FS 25/03/14: Not included in Highland Formulary because not accepted by SMC.
977/14 Not recommended	Lubiprostone, 24 micrograms soft capsules (Amitiza®)	Treatment of chronic idiopathic constipation and associated symptoms in adults	11/08/14	FS 26/08/14: Not included in Highland Formulary because not accepted by SMC.
994/14 Restricted	Lurasidone, 18.5mg, 37mg, 74mg film-coated tablets (Latuda®)	For the treatment of schizophrenia in adults aged 18 years and over.	15/10/14 & 30/10/14	FS 28/10/14: Not included in the Highland Formulary because clinicians do not support Formulary inclusion.
952/14 Accepted restricted with PAS	Macitentan, 10mg film-coated tablets (Opsumit®) (FS 25/03/14)	As monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension in adult patients of World Health Organisation Functional Class II to III.	08/04/14	FS 25/03/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
1042/15 Accepted	Magnesium aspartate dihydrate equivalent to 243mg (10mmol) of magnesium powder for oral solution (Magnaspartate®)	Treatment and prevention of magnesium deficiency, as diagnosed by a doctor.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine: Include in the Highland Formulary for this indication.
837/13 Accepted for restricted use	mannitol 40mg inhalation powder hard capsule (Bronchitol®)	Treatment of cystic fibrosis in adults aged 18 years and above as an add-on therapy to best standard of care	17/09/15	Not included in Highland Formulary because clinicians do not support formulary inclusion.
896/13 Accepted	Medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press)	Long-term female contraception.	17/09/13 & 26/01/16	FS 26/01/16: Include in Highland Formulary for this indication.
935/13 Not recommended	Micronized progesterone 200mg capsules (Utrogestan Vaginal®)	Supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.	28/01/14	Not included in Highland Formulary because not accepted by SMC.

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1094/15 Accepted	Midodrine hydrochloride 2.5mg, 5mg tablets (Bramox®)	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.	27/10/15	FS 27/10/15 Include in Highland Formulary for this indication.
913/13 Accepted	Mifepristone 200mg tablet and misoprostol 0.2mg vaginal tablets combipack (Medabon®)	Medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea.	13/11/14	FS 28/10/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
862/13 Accepted	Mirabegron 25mg and 50mg prolonged-release tablets	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.	28/05/13	Included in Highland Formulary for this indication.
996/14 Accepted	Misoprostol, 200 micrograms, vaginal delivery system (Mysodelle®)	Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.	15/10/14 & 30/10/14	FS 28/10/14: Not included in the Highland Formulary because clinicians do not support Formulary inclusion.
917/13 Accepted	Nalmefene 18mg film-coated tablets (Selincro®)	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.	21/10/13 & 26/11/13 & 28/01/14	Not Included in the Highland Formulary pending protocol.
1106/15 Accepted	Naloxegol 12.5mg and 25mg film-coated tablets (Moventig®)	Treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s).	9/12/15 & 26/01/16	FS 26/01/16: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
979/14 Not recommended	Natalizumab 300mg concentrate for solution for infusion (Tysabri®)	Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over.	24/06/14	FS 24/06/14: Not included in Highland Formulary because not accepted by SMC.
813/12 Accepted	Nepafenac (Nevanac®)	for reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.	27/11/12	FS 27/03/18: Include in Highland Formulary for this indication.
1109/15 Restricted	Netupitant/palonosetron capsule (Akynzeo®)	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.	24/01/2016 & 25/10/16	FS 25/10/16: Include in Highland Formulary for this indication.
1076/15 Restricted	Nintedanib 100mg and 150mg capsules (Ofev®)	In adults for the treatment of idiopathic pulmonary fibrosis (IPF).	27/10/15	FS 27/10/15 Include in Highland Formulary for this indication.

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1027/15 Accepted	Nintedanib 100mg and 150mg soft capsules (Vargatef®)	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.	14/04/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
898/13 Not recommended - non-submission	Nomegestrol acetate/estradiol 2.5 mg/1.5 mg film-coated tablets (Zoely®)	Oral contraception.	17/09/13	Not included in Highland Formulary because not accepted by SMC.
1008/14 Accepted	Obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®)	In combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia.	10/12/14 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
892/13 Accepted Resubmission	Ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®)	Treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns.	11/08/14 & 26/08/14 & 17/09/13 & 13/11/14	FS 28/10/14: Included in the Highland Formulary for this indication.
1037/15 Restricted	Ofatumumab 100mg and 1,000mg concentrate for solution for infusion (Arzerra®)	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.	12/05/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
1047/15 Not recommended	Olaparib, 50mg, hard capsules (Lynparza®)	Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed <i>BRCA</i> -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.	22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
823/12 Accepted	olmesartan medoxomil, amlodipine besilate and hydrochlorothiazide (Sevikar HCT®)	In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.	29/01/13	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
974/14 Accepted Resubmission	Olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®)	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.	12/02/15 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support formulary inclusion.
59/03 Accepted, resubmission	Olopatadine eye drops 1mg/mL	Seasonal allergic conjunctivitis	30/10/14	FS 28/10/14: Included in the Highland Formulary for this indication.
708/11 Restricted Superseded by NICE MTA278	Omalizumab 150mg solution for injection (Xolair®)	Treatment of IgE mediated asthma	13/01/15 & 30/01/15	FS 22/03/2016 Included in Highland Formulary for this indication

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1017/14 Restricted	Omalizumab 150mg solution for injection (Xolair®)	Add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.	13/01/15 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support formulary inclusion.
1051/15 Accepted	Ombitasvir 12.5mg/paritaprevir 75mg/ritonavir 50mg (Viekirax®) film-coated tablet and dasabuvir 250mg (Exviera®) film-coated tablet.	Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with dasabuvir (Exviera®) with or without ribavirin for the treatment of genotype 1 chronic hepatitis.	09/06/15 & 24/03/16	FS 26/05/15: Included in the Highland Formulary for these formulations
912/13 Restricted	Ondansetron 4mg, 8mg orodispersible films (Setofilm®)	Prophylaxis of acute nausea and vomiting.	26/11/13	Not Included in the Highland Formulary because clinicians do not support formulary inclusion.
1071/15 Not recommended	Paclitaxel albumin (Abraxane)	In combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients.	09/06/15	FS 26/05/15: Not included in Highland Formulary because not accepted by SMC.
968/14 Accepted (resubmission)	Paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®)	In combination with gemcitabine for first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	24/06/14 & 12/02/15	FS 23/03/16: Included in the highland Formulary for this indication
1073/15 Accepted	Palonosetron, 250 micrograms solution for injection (Aloxi®)	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.	11/08/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
1082/15 Not recommended (non submission)	Panitumumab (Vectibix®)	Treatment of adult patients with wild-type RAS metastatic colorectal cancer first-line in combination with FOLFIRI.	22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
1048/15 Accepted (PACE)	Pasireotide (as pamoate) 20mg, 40mg 60mg powder and solvent for suspension for injection (Signifor®)	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.	08/09/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
1018/14 Accepted	Peginterferon 63, 94 and 125 microgram solution for injection in pre- filled syringe (Plegridy®)	In adult patients for the treatment of relapsing remitting multiple sclerosis.	13/01/15 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
871/13 Accepted Restricted	Pegylated interferon alfa-2a (Pegasys®)	In combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in	28/05/13 (reported 11/06/13)	Included in Highland Formulary for this indication.

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		treatment-naïve children and adolescents five years of age and older.		
1086/15 Accepted (PACE)	Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)	Monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.	27/01/16 & 10/11/15	FS 26/01/16: Included in the Highland Formulary for this indication.
1087/15 Not recommended (PACE)	Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)	Monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously treated with ipilimumab.	10/11/15	Not included in Highland Formulary because not accepted by SMC.
770/12 Accepted	Pemetrexed, 100mg & 500mg, powder for concentrate for solution for infusion (Alimta®)	Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.	10/12/14 & 30/01/15 & 09/03/15 & 26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
819/12 Accepted Restricted	Perampanel tablets 2mg, 4mg, 6mg, 8mg, 10mg, 12mg (Fycompa)	Adjunctive treatment of partial-onset seizures.	29/01/13 & 26/03/15	FS 24/03/15: Included in the Highland Formulary for this indication.
897/13 Not recommended Resubmission	Pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®)	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.	21/10/13 & 26/11/13 & 13/11/14	FS 28/10/14: Not included in Highland Formulary because not accepted by SMC.
835/13 Accepted with PAS	Pirfenidone 267mg capsule (Esbriet®)	In adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).	17/09/13 & 24/06/14	FS 24/06/14: Included in Highland Formulary for this indication
972/14 Accepted Resubmission	Pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®)	In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment	07/07/14 & 10/12/14 & 30/01/15	FS 27/01/15: Included in the Highland Formulary for this indication.
1032/15 Accepted	Ponatinib 15mg, 45mg film-coated tablets (Iclusig®)	Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML), Philadelphia chromosome positive acute lymphoblastic leukaemia.	14/04/15 & 25/08/15	FS 25/08/15: Formulary medicine: Include in the Highland Formulary for this indication.
999/14 Restricted	Posaconazole 100mg gastro-resistant tablets (Noxafil®)	Treatment or prophylaxis of fungal infections in adults.	15/10/14 & 30/10/14	FS 26/08/14: Included in the Highland Formulary for this indication.
1067/15 Accepted	Posaconazole 300mg concentrate for solution for infusion (Noxafil®)	Treatment of selected fungal infections and prophylaxis of invasive fungal infections.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine: Not included in Highland Formulary for this formulation and indication because clinicians do not support Formulary inclusion.
818/12 Not	Racecadotril 10mg, 30mg granules for	Complementary symptomatic treatment of acute diarrhoea in	11/08/14 & 26/08/14	FS 26/08/14: Not included in Highland

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recommended (resubmission)	oral suspension (Hidrasec Infants®, Hidrasec Children®)	infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition.		Formulary because not accepted by SMC.
1077/15 Accepted	Radium-223 dichloride 1000kBq/mL solution for injection (Xofigo®)	Treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.	27/10/15	FS 27/10/15 Include in Highland Formulary for this indication.
902/13 Restricted	Raltegravir 25mg, 100mg chewable and 400mg film-coated tablets (Isentress®)	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.	17/09/13	Not included in Highland Formulary because clinicians do not support formulary inclusion.
1113/15 Restricted	Raltegravir chewable tablets 25mg, 100mg (Isentress®)	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.	10/11/15	FS 27/10/15 Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1102/15 Restricted	Raltegravir granules for oral suspension 100mg (Isentress®)	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.	10/11/15	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
732/11 Accepted with PAS	Ranibizumab solution for injection 10mg/mL (Lucentis®)	Treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.	28/05/13	Included in Highland Formulary for this indication.
907/13 Accepted with PAS	Ranibizumab, 10mg/mL, solution for injection (Lucentis®)	Treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults.	26/11/13	Included in the Highland Formulary for this indication.
1118/15 Not recommended	Regorafenib 40mg film-coated tablets (Stivarga®)	Adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies.	27/10/15	Not included in Highland Formulary because not accepted by SMC.
1031/15 Accepted	Regorafenib 40mg film-coated tablet (Stivarga®)	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.	14/04/15 & 10/11/15	FS 27/10/15 Include in Highland Formulary for this indication.
876/13 Not recommended	Rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride film-coated tablets	Initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines.	28/05/13	Not included in Highland Formulary for this indication because not accepted by SMC.
893/13 Accepted	Rifaximin 550mg film-coated tablets (Targaxan®)	Reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients	17/09/13	Included in Highland Formulary for this indication.

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		≥18 years of age.		
951/14 Accepted	Rilpivirine 25mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®)	Treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine.	08/04/14	FS 25/03/14: Included in Highland Formulary for this indication.
1001/14 Restricted	Riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®)	Chronic thromboembolic pulmonary hypertension (CTEPH): Treatment of adult patients.	10/12/14 & 30/01/15	FS 27/01/15: Not included in Highland Formulary because clinicians do not support formulary inclusion.
1056/15 Accepted restricted with PAS	Riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®)	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.	22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
975/14 Accepted restricted	Rituximab (Mabthera)	Non-Hodgkin's lymphoma	7/07/14 & 26/08/14	FS 26/08/14: Included in the Highland Formulary for this indication.
894/13 Restricted	Rituximab 100mg, 500mg solution for infusion (MabThera®)	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).	17/09/13	Not included in Highland Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this indication.
1062/15 Not recommended	Rivaroxaban 2.5mg film-coated tablets (Xarelto®)	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.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine: Not included in Highland Formulary for this formulation and indication because not accepted by SMC.
795/12 Accepted with restrictions	rufinamide (Inovelon)	adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older.	14/08/12	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
867/13 Accepted	Ruxolitinib (as phosphate), 5mg, 15mg & 20mg tablets (Jakavi®)	Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis.	09/03/15 & 26/03/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
958/14 Not recommended	Saxagliptin 2.5mg & 5mg film-coated tablets (Onglyza®)	Monotherapy in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.	25/03/14	FS 25/03/14: Not included in Highland Formulary because not accepted by SMC.
870/13 Accepted Restricted	Saxagliptin + metformin (Komboglyze®)	Adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older	28/05/13 (reported 11/06/13)	Not included in Highland Formulary because clinicians do not support

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		with type 2 diabetes mellitus.		formulary inclusion.
918/13 Restricted	Saxagliptin 2.5mg and 5mg film-coated tablets (Onglyza®)	In type 2 diabetes mellitus to improve glycaemic control as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	28/01/14	Not Included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary.
929/13 Accepted	Saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg film-coated tablets (Komboglyze®)	In combination with a sulphonylurea (ie triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus.	28/01/14	Not Included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary.
772/12 Accepted	Saxagliptin, 2.5mg and 5mg, film-coated tablets (Onglyza®)	In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin).	13/11/14	FS 28/10/14: Not included in the Highland Formulary because clinicians do not support formulary inclusion.
1054/15 Restricted	Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx)	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.	09/06/15	FS 26/05/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
809/12 Accepted for restricted use	sildenafil 20mg tablets and 10mg/mL powder for oral solution	Treatment of paediatric patients with pulmonary arterial hypertension.	17/09/15	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
688/11 Accepted with restrictions	sildenafil (Revatio®)	For the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension.	28/06/11	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
988/14 Accepted	Simeprevir 150mg hard capsules (Olysio®)	In combination with other medicinal products for the treatment of chronic hepatitis C in adult patients.	15/10/14 & 30/10/14	FS 26/08/14: Included in the Highland Formulary for this indication.
1083/15 Accepted	Sitagliptin, 25mg, 50mg and 100mg film-coated tablets (Januvia®)	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.	08/09/15	FS 25/08/15: Formulary medicine: include in Formulary for this new indication
914/13 Accepted	Sodium phenylbutyrate granules 483mg/g (Pheburane®)	Adjunctive therapy in the chronic management of urea cycle disorders.	26/11/13	Not Included in the Highland Formulary because clinicians do not support formulary inclusion
964/14 Restricted	Sofosbuvir 400mg tablet (Sovaldi®)	In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.	24/06/14	FS 24/06/14: Included in Highland Formulary for this indication.
945/14	Solifenacin	Treatment of moderate to severe	25/03/14 &	FS 24/03/14: Not

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Accepted	succinate plus tamsulosin hydrochloride 6mg/0.4mg modified release tablet (Vesomni®)	storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.	26/03/15	included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary.
1055/15 Accepted with PAS	Sorafenib 200mg film-coated tablets (Nexavar®)	Treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.	22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.
1035/15 Accepted	Sucroferic oxyhydroxide 500mg chewable tablets (Velphoro®)	For the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).	14/04/15 & 14/11/17	FS 14/11/17: Included in Highland Formulary for this indication
1041/15 Accepted	Tacrolimus (as monohydrate) 0.75mg, 1mg and 4mg prolonged-release tablets (Envarsus®)	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.	14/04/15	FS 24/03/15: Formulary medicine: Not included in Highland Formulary for this formulation/brand because clinicians do not support Formulary inclusion.
710/11 Accepted with restrictions	tadalafil (Adcirca®)	treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II or III, to improve exercise capacity.	28/06/11	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
877/13 Not recommended	Tafamidis meglumine 20mg soft capsules	Treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment.	28/05/13	Not included in Highland Formulary for this indication because not accepted by SMC.
1085/15 Restricted	Tafluprost 15micrograms/mL and timolol 5mg/mL preservative-free eye drops (Taptiqom®)	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.	08/09/15	FS 25/08/15: Formulary medicines: not included in Formulary for this new formulation because clinicians do not support Formulary inclusion
654/10 Accepted Restricted Resubmission	Tapentadol, 50, 100, 150, 200 and 250mg prolonged-release tablets (Palexia® SR)	Chronic pain.	28/06/11 & 29/01/13	Included in Highland Formulary for this indication.
1080/15 Accepted restricted	Tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion	The treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.	11/08/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary for this indication because clinicians do not support Formulary inclusion.

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	(Sivextro®)			
802/12 Accepted with restrictions	Tegafur/gimeracil/oteracil (Teysono®)	Treatment of advanced gastric cancer in adults who are unsuitable for an anthracycline, fluorouracil and platinum triplet first-line regimen.	25/09/12 & 27/10/15	FS 27/10/15 Include in Highland Formulary for this indication.
1015/14 Not recommended	Telavancin hydrochloride 250mg and 750mg powder for concentrate for solution for infusion (Vibativ®)	Treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA).	13/11/14	FS 28/10/14: Not included in Highland Formulary because not accepted by SMC.
900/13 Restricted	Tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tablets (Viread®)	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.	17/09/13	Not included in Highland Formulary because clinicians do not support formulary inclusion.
904/13 Restricted	Tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Viread®)	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.	17/09/13	Not included in Highland Formulary because clinicians do not support formulary inclusion.
905/13 Restricted	Tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®)	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	17/09/13	Not included in Highland Formulary because clinicians do not support formulary inclusion.
940/14 Restricted	Teriflunomide, 14mg, film-coated tablets (Aubagio®)	Treatment of adults with relapsing remitting multiple sclerosis (MS).	25/03/14 & 24/06/14	FS 24/06/14: Included in Highland Formulary for this indication.
1000/14 Not recommended (Non submission)	Tetracaine/lidocaine 70mg/g + 70mg/g (Pliaglis 70mg/g + 70mg/g cream®)	Local dermal anaesthesia on intact skin prior to dermatological procedures in adults.	15/10/14 & 30/10/14	FS 26/08/14: Not included in Highland Formulary because not accepted by SMC.
1101/15 Not recommended (non-submission)	Tigecycline 50mg powder for solution for infusion (Tygacil®)	Treatment in children from the age of eight years for infections.	08/09/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
941/14 Accepted restricted	Timolol, 1mg/g eye gel for single-dose container (Tiopex®)	Reduction of the elevated intraocular pressure in patients with ocular hypertension, chronic open angle glaucoma.	25/03/14	FS 25/03/14: Included in the Highland Formulary for this indication.
868/13 Not recommended	Timothy grass pollen allergen 75,000 SQ-T oral	Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children	28/05/13	Not included in Highland Formulary because not accepted by SMC.

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(non submission)	lyophilisate (GRAZAX®)	(5 years or older).		
1061/15 Accepted with PAS	Tinzaparin 20,000 IU/mL 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL and 0.9mL pre-filled syringe (Innohep Syringe®)	Patients with solid tumours: Extended treatment of symptomatic venous thrombo-embolism (VTE) and prevention of its recurrence.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine (for renal use only pre-filled syringe 2500u/0.25mL, 3500u/0.35mL, 4500u/0.45mL) Not included in Highland Formulary for this indication and these formulations because clinicians do not support Formulary inclusion.
1028/15 Accepted	Tiotropium 2.5 microgram solution for inhalation (Spiriva® Respimat®)	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.	11/08/15& 25/08/15	FS 25/08/15: Formulary medicine: Included in the Highland Formulary for this indication.
1099/15 Accepted	Tiotropium/olodaterol 2.5 microgram/2.5 microgram inhalation solution (Spiolto® Respimat®)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	27/10/15 & 10/11/15 & 24/05/16	FS 24/05/16: Included in the Highland Formulary for this indication.
SMC 783/12 HIS / NICE MTA 276	Tobramycin dry powder for inhalation	Treatment of chronic pulmonary infection caused by <i>Pseudomonas aeruginosa</i> in people with cystic fibrosis.	19/09/13 & 21/10/13 & 26/11/13	Included in Highland Formulary for this indication.
1020/14 Not recommended	Tocilizumab 20mg/mL concentrate for solution for infusion (RoActemra®)	Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.	10/12/14 & 30/01/15	27/01/15: Formulary medicine. Not included in Highland Formulary for this indication because not accepted by SMC.
982/14 Accepted restricted	Tocilizumab, 162mg, solution for injection in pre-filled syringe (RoActemra®)	In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients.	11/08/14 & 26/08/14	FS 26/08/14: Included in the Highland Formulary for this indication.
930/13 Accepted	Tocilizumab, 20mg/mL concentrate for infusion (RoActemra®)	Tocilizumab in combination with methotrexate is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older.	28/01/14	Included in the Highland Formulary for the indication in question
928/13 Restricted	Trastuzumab 6000mg/5mL solution for injection (Herceptin®)	For subcutaneous administration in adult patients with HER2 positive metastatic breast cancer and early breast cancer in a range of settings.	28/01/14	Included in Highland Formulary for this indication.
623/10 Restricted (resubmission)	Trastuzumab, 150mg powder for concentrate for solution for infusion (Herceptin®)	In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not	27/10/15	FS 27/10/15 Include in Highland Formulary for this indication.

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		received prior anti-cancer treatment.		
1091/15 Accepted	Travoprost 40 micrograms/mL eye drops (Travatan®)	Decrease of elevated intraocular pressure in paediatric patients aged 2 months to <18 years with ocular hypertension or paediatric glaucoma.	27/10/15	FS 27/10/15: Not included in Highland Formulary because clinicians do not support Formulary inclusion.
1103/15 Accepted	Triamcinolone hexacetonide 20mg/mL suspension for injection	Juvenile idiopathic arthritis (JIA).	10/11/15	FS 27/10/15 Not included in Highland Formulary because clinicians do not support Formulary inclusion.
834/13 Accepted	Ulipristal tablets 5mg (Esmya®)	Pre-operative treatment of moderate to severe symptoms of uterine fibroids.	26/03/15 & 26/03/13	FS 24/03/15: Included in the Highland Formulary for this indication.
1004/14 Accepted	Umeclidinium, 55 micrograms, powder for inhalation (Incruse®)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	10/12/14 & 30/01/15 & 27/10/15	FS 27/10/15: Include in Highland Formulary for this indication.
978/14 Accepted (resubmission)	Umeclidinium/vilanterol, 55/22 micrograms, inhalation powder (Anoro®)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	12/02/15 & 25/08/15	FS 25/08/15: Included in the Highland Formulary for this indication
889/13 Accepted	Ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®)	For the dissolution of cholesterol gallstones in the gall bladder.	17/09/13	Not included in Highland Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this indication.
944/14 Accepted Restricted	Ustekinumab 45mg solution for injection in pre-filled syringe (Stelara®)	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate.	25/03/14 & 24/06/14	FS 24/03/14: Included in Highland Formulary for this indication
1045/15 Accepted	Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®)	Treatment of adult patients with moderately to severely active ulcerative colitis.	12/05/15 & 28/05/15	FS 26/05/15: Included in the Highland Formulary for this indication.
1064/15 Accepted restricted with PAS	Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®)	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.	22/07/15 & 25/08/15	FS 25/08/15: Formulary medicine: Included in the Highland Formulary for this indication.

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681/11 Accepted	velaglucerase alfa (VPRIV®)	long-term enzyme replacement therapy in patients with type 1 Gaucher disease.	27/11/12	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
792/12 Accepted with PAS	Vemurafenib tablet 240mg (Zelboraf®)	Monotherapy for use in first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma.	28/01/14	Included in Highland Formulary for this indication.
826/12 Recommended	vildagliptin (Galvus®)	SMC accepted vildagliptin for restricted use in the treatment of type 2 diabetes mellitus in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.	29/01/13	Not included in Highland Formulary because clinicians do not support Formulary inclusion.
875/13 Restricted	Vildagliptin 50mg tablets (Galvus®)	Triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.	28/05/13 & 28/01/14	Not Included in the Highland Formulary because the decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the Formulary
874/13 Not recommended (non-submission)	Vildagliptin/metformin in hydrochloride 50 mg/850 mg and 50 mg/1000 mg film-coated tablets	Treatment of type 2 diabetes mellitus.	28/05/13	Not included in Highland Formulary for this indication because not accepted by SMC.
686/11 . Not recommended Resubmission	Vinflunine (as ditartrate), 25mg/mL, concentrate for solution for infusion (Javlor®)	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.	22/07/15 & 25/08/15	FS 25/08/15: Not included in Highland Formulary because not accepted by SMC.
924/13 Not recommended Non-submission	Vismodegib 150 mg hard capsules (Erivedge®)	Treatment of adult patients with: symptomatic metastatic basal cell carcinoma, locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy.	21/10/13 & 26/11/13	Not included in Highland Formulary because not accepted by SMC.
1014/14 Not recommended	Voriconazole 50mg and 200mg film-coated tablets/200mg powder for solution for infusion/200mg powder and solvent for solution for infusion /40mg/mL powder for oral suspension (Vfend®)	Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients.	13/11/14	FS 28/10/14: Formulary medicine: not included in Highland Formulary for this indication because not accepted by SMC.

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949/14 Restricted	Zonisamide 25mg, 50mg and 100mg capsules (Zonegran®)	Adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above.	25/03/14	FS 25/03/14: Included in the Highland Formulary for this indication.
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