Area Drug and Therapeutics Committee
Cumulative list of decisions on SMC Accepted Medicines from 1st April 2012
January 2018

SMC Number/ date received	SMC Accepted Medicine	Indication See SMC website for more detailed information (www.scottishmedicines.org.uk)	NHS Ayrshire & Arran Formulary Decision/ rationale/ date	Date decision issued
811/12 9th November 2012	5-aminolaevulinic acid (as hydrochloride), 78mg/g, gel (Ameluz®)	Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 21st January 2013	22nd January 2013
719/11 resub 8th March 2013	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 TNF-alpha inhibitor. **SMC restriction:** abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 1st May 2013	13th May 2013
888/13 5th July 2013	Abatacept 125mg/mL solution for subcutaneous injection in a pre-filled syringe (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 TNF-alpha inhibitor. **SMC restriction:** abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 14th August 2013	26th August 2013
764/12 (resub) 6th July 2012	Abiraterone acetate 250mg tablets (Zytiga®)	With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen	**Include** Pending protocol 3rd September 2012	13th September 2012
			Include Consultant initiation as per West of Scotland Cancer Network protocol Case by case form must be completed before prescribing can be initiated 14th January 2013	22nd January 2013
			Include Consultant initiation, as per West of	20th May 2015

			Scotland Cancer Network protocol 11th May 2015	
873/13 (resub) 4th September 2015	Abiraterone acetate 250mg tablets(Zytiga®)	Abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd November 2015	16th November 2015
			Include Consultant initiation as per West of Scotland Cancer Network protocol 8th February 2016	11th February 2016
810/12 5th October 2012	Aclidinium 322 micrograms inhalation powder (Eklira Genuair®)	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)	**Include** 5th December 2012	17th December 2012
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance guidance) 8th May 2017	22nd May 2017
1034/15 6th March 2015	Aclidinium/formoterol fumarate dihydrate 340/12 micrograms inhalation powder (Duaklir Genuair®)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease	**Include** Second choice within therapeutic class 3rd June 2015	15th June 2015
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance guidance) 8th May 2017	22nd May 2017
858/13 8th March 2013	Adalimumab, 40mg/0.8mL, solution for injection (Humira®)	Treatment of adults with severe axial spondylo-arthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein and/or magnetic resonance imaging, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs.	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated in the interim	13th May 2013

			29th April 2013	
880/13 7th June 2013	Adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®)	Treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies. **SMC restriction:** prescribing by specialists in paediatric gastroenterology.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 14th August 2013	26th August 2013
881/13 7th June 2013	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 (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 2 years.**SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 14th August 2013	26th August 2013
1050/15 10th April 2015	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. **SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology).	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 3rd June 2015	15th June 2015
1068/15 5th June 2015	Adalimumab (Humira®) 40 mg/0.8 ml 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. **SMC restriction:** Patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score of ≥10 and a Dermatology Life Quality Index (DLQI) of >10.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 27th August 2015	1st September 2015
1143/16 8th April 2016	Adalimumab 40mg/0.8mL solution for injection (Humira®)	Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th	15tth June 2016

			September 2016 6th June 2016	
			Available in line with local guidance for prescribing 1st August 2016	15th August 2016
1243/17 5th May 2017	Adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL vial for paediatric use	Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th August 2017 7th June 2017	21st June 2017
			Routinely available in line with local guidance 22nd August 2017	23rd August 2017
682/11 resub 7th March 2014	Adapalene 0.1%/ benzoyl peroxide 2.5% gel (Epiduo®)	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. **SMC restriction:** the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate.	**Include** 4th June 2014	17th June 2014
920/13 7th February 2014	Afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®)	As 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).	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 7th April 2014	10th April 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
857/13 8th March 2013	Aflibercept 40mg/mL solution for intravitreal injection (Eylea®)	In adults for the treatment of neovascular (wet) age-related macular degeneration	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated in the interim 29th April 2013	13th May 2013
			Include	26th August

			Pending protocol Case by case form requires to be completed before treatment is initiated in the interim 12th August 2013	2013
954/14 7th March 2014	Aflibercept, 40mg/mL solution for injection (Eylea®)	Adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd April 2014	10th April 2014
878/13 resub 7th February 2014	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.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 7th April 2014	10th April 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1003/14 10th October 2014	Aflibercept, 40mg/mL solution for injection (Eylea®)	Adults for the treatment of visual impairment due to diabetic macular oedema (DMO). **SMC restriction:** treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 5th November 2014	19th November 2014
1074/15 7th August 2015	Aflibercept 40mg/mL solution for injection (Eylea®)	Adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd September 2015	14th September 2015
1186/16 9th September 2016	Aflibercept 40mg/mL solution for injection (Eylea®)	Adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV).	Available in line with local guidance for prescribing 10th October 2016	18th October 2016
1024/15 4th December	Albiglutide 30mg and 50mg pre-filled pen (Eperzan®)	Treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when these, together	**Exclude** Pending protocol (Joint Formulary)	16th March 2016

2015		with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** an alternative once weekly glucagon-like peptide-1 (GLP-1) agonist for use in combination with oral anti-diabetic agents as a third-line pre-insulin treatment option.	2nd March 2016	
959/14 6th June 2014	Alemtuzumab, 12mg, concentrate for solution for infusion (Lemtrada®)	For adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 1st September 2014	24th October 2014
1137/16 4th March 2016	Alendronic acid 70mg effervescent tablet (Binosto®)	Treatment of postmenopausal osteoporosis. **SMC restriction:** for use in patients who are unable to swallow tablets where alendronic acid is the appropriate treatment choice	Available in line with local guidance for prescribing 4th May 2016	12th May 2016
1147/16 8th July 2016	Alirocumab 75mg and 150mg solution for injection in pre-filled pen (Praluent®)	Adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. **SMC restriction:** for specialist use only in patients at high cardiovascular risk as follows: - patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, - patients with HeFH and LDL-C ≥3.5mmol/L, for secondary prevention of cardiovascular events or, - patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L or, - patients with recurrent/ polyvascular disease and LDL-C ≥3.5mmol/L.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 10th October 2016 1st August 2016	15th August 2016
			Available in line with local guidance for prescribing 10th October 2016	18th October 2016
937/14 resub 8th August 2014	Alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®)	Adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** dual therapy	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 10th October 2014	24th October 2014

		• In combination with metformin, when metformin alone, together with diet and exercise does not provide adequate glycaemic control in patients for whom the addition of a sulfonylurea is inappropriate. • In combination with a sulfonylurea, when sulfonylurea alone, together with diet and exercise does not provide adequate glycaemic control in patients		
998/14 5th September 2014	Alogliptin 12.5mg plus metformin1000mg combination tablet (Vipdomet®)	Treatment of adult patients aged 18 years and older with type 2 diabetes mellitus: • as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin. • in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone. • in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. **SMC restriction:** to use in patients for whom this fixed dose combination of alogliptin and metformin is an appropriate choice of therapy and only when the addition of a sulphonylurea to metformin monotherapy is not appropriate.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 10th October 2014	24th October 2014
714/11 4th May 2012	Alteplase, 10mg, 20mg, 50mg, powder and solvent for solution for injection and infusion (Actilyse®)	Fibrinolytic treatment of acute ischaemic stroke. Treatment must be started as early as possible within 4.5 hours after onset of the stroke symptoms and after exclusion of intracranial haemorrhage by appropriate imaging techniques (e.g. cranial computerised tomography or other diagnostic imaging method sensitive for the presence of haemorrhage).	**Include** Consultant stroke physician initiation, as per local protocol 6th June 2012	20th June 2012
836/13 11th January 2013	Apixaban 2.5mg and 5mg film-coated tablets (Eliquis®)	Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation, with one or more risk factors, such as prior stroke or transient ischaemic attack; age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II).	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated in the interim 4th March 2013	15th March 2013
			Available in line with local guidance for	18th May 2016

			prescribing 7th March 2016	
1029/15 6th February 2015	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.	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment initiation 6th May 2015	20th May 2015
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Joint Formulary) 11th January 2017	24th January 2017
1052/15 8th May 2015	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 including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA).	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 1st June 2015	15th June 2015
1053/15 8th May 2015	Apremilast 10mg, 20mg, 30mg tablets (Otezla®)	Alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. **SMC restriction:** for use in adult patients with active PsA who have had an inadequate response with at least two prior DMARD therapies or who are intolerant to such therapies.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 1st June 2015	15th June 2015
1241/17 5th May 2017	Aprepitant, 80mg, 125mg hard capsules and 125mg powder for oral suspension (Emend®)	As part of combination therapy, for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in infants, toddlers and children from the age of six months to less than 12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules).	Routinely available from a specialist centre in another health board 7th June 2017	21st June 2017
1252/17 9th June 2017	Aprepitant (Emend) 80mg, 125mg hard capsules; aprepitant (Emend®) 125mg powder for oral suspension	As part of combination therapy, for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy in children, toddlers and infants from the age of six months to <12 years (powder for oral suspension) and	Routinely available from a specialist centre in another health board 9th August 2017	23rd August 2017

		adolescents from the age of 12 years to 17 years (hard capsules).		
812/12 resub 5th July 2013	Argatroban, 100mg/ml, concentrate for solution for infusion (Exembol®)	Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.	**Include** Specialist consultant initiation 14th August 2013	26th August 2013
891/13 9th August 2013	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. **SMC restriction:** restricted to initiation and management under the supervision of a child/adolescent psychiatrist.	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
962/14 4th April 2014	Aripiprazole 400mg powder and solvent for prolonged release suspension for injection (Abilify Maintena®)	Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.	**Include** Consultant initiation 4th June 2014	17th June 2014
1098/15 9th October 2015	Atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®)	In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 4th November 2015	16th November 2015
909/13 4th October 2013	Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®)	Treatment of attention-deficit/hyperactivity disorder in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed.	**Exclude** Pending protocol (Joint Formulary) 4th December 2013	18th December 2013
1107/15 6th November 2015	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. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD. **SMC restriction:** to use in patients who are unable to swallow capsules.	**Include** Consultant initiation 6th January 2016	20th January 2016
SMC 1284/17	Aviptadil / phentolamine 25 micrograms / 2mg solution for injection (Invicorp®)	Symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology. SMC restriction: for use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors) and other non-injectable formulations of erectile dysfunction medications.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th February 2018 6th December 2017	21st December 2017

855/13 resub 4th October 2013	Axitinib, 1mg and 5mg, film-coated tablets (Inlyta®)	Treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine	**Include** Pending West of Scotland Cancer Network protocol Case by case form requires to be completed before treatment is initiated in the interim 11th November 2013	18th November 2013
			Include Consultant initiation as per West of Scotland Cancer Network protocol 12th March 2014	24th March 2014
950/14 7th March 2014	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.	**Include** Specialist Consultant initiation (Microbiology or Infectious Diseases) 7th May 2014	19th May 2014
921/13 resub 5th September 2014	Azelastine hydrochloride 137micrograms plus fluticasone propionate 50micrograms per actuation nasal spray (Dymista® nasal spray)	Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	**Include** 5th November 2014	19th November 2014
753/12 resub 5th December 2014	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 aged six years and older. **SMC restriction:** When inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit (measured as _2% decline in forced expiratory volume in 1 second [FEV1]).	**Include** Consultant initiation, as per SMC restrictions 4th March 2015	16th March 2015
1265/17 11th September 2017	Baricitinib 2mg and 4mg film-coated tablet (Olumiant®)	Treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Baricitinib may be used as monotherapy or in combination with methotrexate. **SMC restriction:** In patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a TNF antagonist, it may be used in patients ineligible to receive rituximab.	Routinely available in line with local guidance 13th September 2017	20th September 2017
976/14	Beclometasone dipropionate	Symptomatic treatment of patients with severe COPD (FEV1	**Include**	22nd August

6th June 2014	and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®)	<50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	13th August 2014	2014
1274/17 9th October 2017	Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 87 micrograms / 5 micrograms / 9 micrograms metered dose inhaler (Trimbow®)	Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. **SMC restriction:** severe COPD (forced expiratory volume in one second less than 50% predicted normal).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th December 2017 4th October 2017	13th October 2017
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Joint Formulary) 6th December 2017	21st December 2017
775/12 resubmission 7th April 2017	Belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®)	Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. **SMC restriction:** patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th August 2017 8th May 2017	22nd May 2017
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance) 10th August 2017	23rd August 2017
1063/15 7th August 2015	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 who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents. **SMC restriction:** to use in combination with paclitaxel.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 7th September 2015	14th September 2015
			Available in line with local guidance for prescribing	20th September 2016

			29th August 2016	
806/12 resub 9th October 2015	Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®)	In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. **SMC restriction:** In patients with FIGO stage IV disease	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd November 2015	16th November 2015
			Available from a specialist centre in another NHS board 9th May 2016	12th May 2016
1135/16 8th April 2016	Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®)	In combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. **SMC Restriction:** for use in combination with cisplatin and paclitaxel	Available from a specialist centre in another NHS board 9th May 2016	12th May 2016
839/13 8th February 2013	Bimatoprost 0.3mg/mL single-dose eye drops (Lumigan UD®)	Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers). **SMC restriction:** to use in patients who have proven sensitivity to the preservative benzalkonium chloride.	**Include** Specialist initiation as per SMC restrictions 6th March 2013	15th March 2013
906/13 6th September 2013	Bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eye-drops (Ganfort® Unit Dose Preservative Free)	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. **SMC restriction:** to use in patients who have proven sensitivity to preservatives	**Include** Specialist initiation as per SMC restrictions 6th November 2013	18th November 2013
1145/16 6th May 2016	Blinatumomab, 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®)	Treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by5th September 2016 6th June 2016	15th June 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
822/12 9th November	Bortezomib (Velcade®) 3.5mg powder for	In combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are	**Include**	17th December 2012

2012	subcutaneous injection	not eligible for high-dose chemotherapy with bone marrow transplant As monotherapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation.	Specialist consultant initiation 5th December 2012	
927/13 6th December 2013	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 who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation. **SMC restriction:** use as triple therapy in combination with dexamethasone and thalidomide.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 27th January 2014	10th February 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1075/15 7th August 2015	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.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 7th September 2015	14th September 2015
			Available in line with local guidance for prescribing 9th May 2016	12th May 2016
910/13 resub 9th January 2015	Bosutinib 100mg, 500mg film-coated tablets (Bosulif®)	Treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd March 2015	16th March 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
916/13 6th September 2013	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, who are	**Include** Pending protocol 2nd October 2013	16th October 2013

		not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required		
931/13 resub 6th June 2014	Botulinum toxin type A powder for solution for injection (BOTOX®)	The management of bladder dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency. **SMC restriction:** Patients who have failed appropriate oral treatment options.	**Include** Consultant initiation as per local guideline 13th August 2014	22nd August 2014
692/11 resubmission 13th January 2017	Botulinum toxin A, 50 Allergan units, 100 Allergan units, 200 Allergan units, powder for solution for injection (Botox®)	Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). **SMC restriction:** use in adults with chronic migraine whose condition has failed to respond to ≥3 prior oral prophylactic treatments, where medication overuse has been appropriately managed.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th April 2017 1st February 2017	15th February 2017
			Routinely available in line with local guidance 5th April 2017	19th April 2017
845/12 resub 5th September 2014	Brentuximab vedotin (Adcetris®) 50mg powder for concentrate for solution for infusion	Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). **SMC restriction:** treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma: 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option	**Include** Specialist use Case by case form requires to be completed before treatment initiation 15th December 2014	17th December 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
991/14 10th October 2014	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.	**Include** Specialist initiation 5th November 2014	19th November 2014
1016/14 5th December 2014	Brimonidine, 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®)	Symptomatic treatment of facial erythema of rosacea in adult patients.**SMC restriction:** for use in patients with moderate to severe persistent facial erythema associated with rosacea.	**Include** As per SMC restrictions 4th February 2015	16th February 2015
1160/16	Brivaracetam 10mg, 25mg, 75mg, 100mg film-coated	Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent	Not routinely available as local implementation plans are being	15th August 2016

10th June 2016	tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®)	patients from 16 years of age with epilepsy. **SMC restriction:** for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th September 2016 10th August 2016	
			Available in line with local guidance for prescribing 7th September 2016	20th September 2016
828/12 7th December 2012	Budesonide 3mg gastro-resistant capsule (Budenofalk ®)	Symptomatic relief of chronic diarrhoea due to collagenous colitis.	**Include** Specialist consultant initiation 6th February 2013	20th February 2013
831/12 7th December 2012	Budesonide 9mg gastro-resistant granules (Budenofalk ®)	Induction of remission in patients with active collagenous colitis	**Include** Specialist consultant initiation 6th February 2013	20th February 2013
970/14 9th May 2014	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.	**Include** Specialist consultant initiation 4th June 2014	17th June 2014
1043/15 10th April 2015	Budesonide, 3mg, gastro-resistant capsules (Budenofalk®)	Use in non-cirrhotic patients who are intolerant of conventional oral corticosteroids (prednisolone) with severe corticosteroid-related side effects (actual or anticipated) such as psychosis, poorly controlled diabetes or osteoporosis	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 3rd June 2015	15th June 2015
1093/15 resub 9th September 2016	Budesonide 9mg prolonged release tablet (Cortiment®)	In adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient. **SMC restriction:** for use in patients with UC who present with active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone, as an alternative to budesonide rectal formulations or off-label oral budesonide.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th December 2016 5th October 2016	18th October 2016
			Available in line with local guidance for prescribing 7th December 2016	19th December 2016
1244/17 5th May 2017	Budesonide/formoterol 100 micrograms/6 micrograms and 200 micrograms/6 micrograms inhalation powder (Symbicort®	The regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" short-acting β2 adrenoceptor agonists, or patients already adequately controlled	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th	21st June 2017

	SMART®)	on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.	August 2017 7th June 2017	
			Routinely available in line with national guidance (adolescents aged 12 to <18 years only) 1st November 2017	22nd November 2017
1213/17 9th December 2016	Buprenorphine 5, 10, 15 and 20 microgram/hour transdermal patch (Butec®)	In adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. **SMC restriction:** for use in elderly patients (over 65 years).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 1st March 2017 11th January 2017	24th January 2017
			Routinely available in line with national guidance 1st February 2017	15th February 2017
1245/17 5th May 2017	Buprenorphine 2mg, 8mg oral lyophilisate (Espranor®)	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction. **SMC restriction:** to patients in whom methadone is not suitable.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th September 2017 7th June 2017	21st June 2017
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Joint Formulary) 10th January 2018	24th January 2018
735/11 resubmission 4th November 2016	Cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®)	Cabazitaxel in combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. **SMC restriction:** for use in patients who have received at least 225mg/m^2 (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.	Available in line with local guidance for prescribing 5th December 2016	19th December 2016
1234/17 5th May 2017	Cabozantinib 20mg, 40mg and 60mg film-coated tablets (Cabometyx®)	Treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.	Routinely available from a specialist centre in another health board 20th June 2017	21st June 2017

814/12 resub 9th August 2013	Caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®)	Treatment of primary apnoea of premature newborns	**Include** Specialist initiation 6th November 2013	18th November 2013
1182/16 5th August 2016	Calcipotriol 50 micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®)	Topical treatment of psoriasis vulgaris in adults.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2nd November 2016 7th September 2016	20th September 2016
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance) 2nd November 2016	16th November 2016
890/13 5th July 2013	Calcium polystyrene sulphonate powder for oral/rectal suspension (Sorbisterit®)	Treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment	**Include** Pending protocol 14th August 2013	26th August 2013
1133/16 4th March 2016	Camellia sinensis (green tea) leaf extract 10% ointment (Catephen®)	Cutaneous treatment of external genital and perianal warts (*condylomata acuminata*) in immunocompetent patients from the age of 18 years. **SMC restriction:** for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin.	Available in line with local guidance for prescribing 4th May 2016	12th May 2016
963/14 9th May 2014	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, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** to use in the following situations: • dual therapy in combination with metformin • triple therapy in combination with metformin plus standard of care • add-on to insulin therapy in combination with insulin plus standard of care	**Include** Consultant initiation Second choice within therapeutic class 4th June 2014	17th June 2014
1019/14	Canagliflozin plus metformin	In adults aged 18 years and older with type 2 diabetes mellitus	**Include**	16th February

5th December 2014	50mg/850mg and 50mg/1000mg immediate release tablets (Vokanamet®)	as an adjunct to diet and exercise to improve glycaemic control: • in patients not adequately controlled on their maximally tolerated doses of metformin alone; • in patients on their maximally tolerated doses of metformin along with other glucose lowering medicinal products, including insulin, when these do not provide adequate glycaemic control; • in patients already being treated with the combination of canagliflozin and metformin as separate tablets. **SMC restriction:** use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy	Consultant initiation Second choice within therapeutic class 4th February 2015	2015
673/11 resub 5th September 2014	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. **SMC restriction:** to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments	**Include** Consultant initiation 10th October 2014	24th October 2014
1242/17 7th July 2017	Carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®).	In combination with dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 4th October 2017 22nd August 2017	23rd August 2017
			Routinely available in line with local guidance 13th September 2017	20th September 2017
899/13 6th September 2013	Carglumic acid 200mg dispersible tablets (Carbaglu®)	Hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
830/12 7th December 20127	Ceftaroline fosamil, 600mg, powder for concentrate for solution for infusion (Zinforo®)	Treatment of complicated skin and soft tissue infections in adults. **SMC restriction:** use in patients with known or suspected meticillin resistant *Staphylococcus aureus* (MRSA) infection in the following settings: • For Gram-positive only infections where vancomycin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv or linezolid iv is normally used. • For polymicrobial Gram-positive and common Gram-negative pathogens*, where vancomycin iv in combination	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 6th February 2013	20th February 2013

		with gentamicin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv in combination with gentamicin iv, or linezolid iv in combination with gentamicin iv, or tigecycline iv is normally used. Ceftaroline should be used only on the advice of local microbiologists or specialists in infectious disease.		
943/14 5th June 2015	Ceftobiprole, 500mg, powder for concentrate for solution for infusion (Zevtera®)	Treatment of the following infections in adults: • Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) • Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents. **SMC restriction:** for use in the treatment of HAP (excluding VAP) when activity is required against suspected methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative pathogens (including *Pseudomona aeruginosa*, *Escherichia coli* and *Klebsiella pneumoniae*) and when combination treatment that includes vancomycin or teicoplanin is inappropriate or has not been tolerated, or when treatment modification is required, i.e. as an alternative to linezolid-based regimens.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary (Joint Formulary) 27th August 2015	1st September 2015
932/13 resubmission 4th November 2016	Cefuroxime 50mg powder for solution for injection (Aprokam®)	Antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.	Available in line with local guidance for prescribing 7th December 2016	19th December 2016
1097/15 6th November 2015	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.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
			Available in line with local guidance for prescribing 29th August 2016	20th September 2016
960/14 4th April 2014	Certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®)	Treatment of adult patients with severe active axial spondyloarthritis, comprising: • Ankylosing spondylitis (AS) Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). • Axial spondyloarthritis without radiographic evidence of AS	**Include** Consultant initiation Case by case form requires to be completed before treatment initiation 7th May 2014	19th May 2014
			Include	14th April 2015

		(nr-axSpA) Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and /or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.	Consultant initiation, as per approved guideline 1st April 2015	
973/14 6th June 2014	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. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **SMC restriction:** Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.	**Include** Consultant initiation Case by case form requires to be completed before treatment initiation 13th August 2014	22nd August 2014
1012/14 5th December 2014	Cetuximab, 100mg/20mL and 500mg/100mL solution for infusion (Erbitux®)	Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer: • in combination with irinotecan-based chemotherapy • in first-line in combination with FOLFOX; • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. **SMC restriction:** for use in patients with RAS wild-type metastatic colorectal cancer, in combination with irinotecan or oxaliplatin-based chemotherapy, in patients who have not previously received chemotherapy for their metastatic disease (first-line treatment).	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd February 2015 Advice superseded by NICE MTA 349	16th February 2015
1011/14 7th November 2014	Cholecalciferol 25,000 international units oral solution (InVita D3®)	Prevention and treatment of vitamin D deficiency.	**Include** 3rd December 2014	17th December 2014
1089/15 4th September 2015	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	**Include** Consultant initiation 2nd December 2015	16th December 2015
1256/17 9th June 2017	Ciprofloxacin 3mg/mL + dexamethasone 1mg/mL ear drops (Cilodex®)	Treatment of the following infections in adults and children: • Acute otitis media in patients with tympanostomy tubes (AOMT) • Acute otitis externa **SMC restriction:** Treatment of acute otitis media in patients with tympanostomy tubes (AOMT).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th September 2017 9th August 2017	23rd August 2017

			Routinely available in line with local guidance 6th September 2017	20th September 2017
1010/14 7th November 2014	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.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 4th February 2015	16th February 2015
			Include ADTC 20th June 2016	15th August 2016
353/07 resub 7th December 2012	Clostridium botulinum type A toxin-haemagglutinin complex 300 units and 500 units (Dysport®)	For focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy. **SMC restriction:** for focal spasticity of the upper limbs associated with stroke.	**Exclude** Pending protocol (Joint Formulary) 6th February 2013	20th February 2013
316/06 resubmission 6th May 2016	Co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®)	Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. **SMC restriction:** for use in patients not eligible for deep brain stimulation	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th September 2016 6th June 2016	15th June 2016
			Available in line with local guidance for prescribing 1st August 2016	15th August 2016
801/12 10th August 2012	Colecalciferol 800 international units (equivalent to 20 micrograms vitamin D3) capsules (Fultium-D3®)	In adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.	**Include** Pending protocol 3rd October 2012	11th October 2012
			Exclude Clinicians do not support the formulary inclusion (Joint Formulary) 6th February 2013	20th February 2013
840/13 11th January 2013	Colecalciferol 800 international units (equivalent to 20 micrograms vitamin D3) tablets (Desunin 800 IU®)	Prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered.	**Include** 6th February 2013	20th February 2013
715/11 (resub)	Collagenase clostridium	Treatment of Dupuytren's contracture in adult patients with a	**Exclude**	20th June 2012

5th April 2012	histolyticum 0.9mg powder and solvent for solution for injection (Xiapex®)	palpable cord. **SMC restriction:** restricted to use as an alternative to limited fasciectomy in adult patients with Dupuytren's contracture of moderate severity (as defined by the British Society for Surgery of the Hand (BSSH), with a palpable cord and up to two affected joints per hand, who are suitable for limited fasciectomy, but for whom percutaneous needle fasciotomy is not considered a suitable treatment option	Pending protocol (Joint Formulary) 11th June 2012	
865/13 resub 6th September 2013	Crizotinib, 200mg and 250mg, hard capsule (Xalkori®)	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer	**Include** Pending protocol 7th October 2013	16th October 2013
			Include Consultant initiation as per West of Scotland Cancer Network protocol Case by case form must be completed before prescribing can be initiated 12th March 2014	24th March 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1152/16 10th June 2016	Crizotinib, 200mg and 250mg hard capsule (Xalkori®)	First-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2nd November 2016 1st August 2016	15th August 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
995/14 5th September 2014	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.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 10th October 2014	24th October 2014
1023/15	Dabrafenib, 50mg and 75mg hard capsules (Tafinlar®)	Monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. **SMC**	**Include**	16th March 2015

6th February 2015		**restriction:** for use in patients with unresectable or metastatic BRAFV600 mutation-positive metastatic melanoma who have received no prior therapy.	Pending protocol Case by case form requires to be completed before treatment initiation 2nd March 2015	
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1002/14 10th October 2014	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. **SMC restriction:** use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis.	**Include** Specialist use only Case by case form requires to be completed before treatment initiation 15th December 2014	17th December 2014
			Routinely available in line with national guidance (NHS Scotland Hepatitis C January 2017 guidelines) 6th March 2017	15th March 2017
1216/17 10th March 2017	Daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®)	In adult patients for the treatment of relapsing forms of multiple sclerosis. **SMC restriction:** for use • in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or • in patients with RRMS with an inadequate response to disease modifying therapy	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th June 2017 5th April 2017	19th April 2017
			Routinely available in line with local guidance 8th May 2017	22nd May 2017
1105/15 9th December 2016	Dalbavancin 500mg powder for concentrate for solution for infusion (Xydalba®)	Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. **SMC restriction:** • for second-line use or when meticillin-resistant *Staphylococcus aureus* (MRSA) infection is suspected, or on the advice of local microbiologists or specialists in infectious disease, and • the patient is initially hospitalised due to ABSSSI, requires intravenous antibiotics, but is eligible for early discharge as soon as their medical condition does not require further inpatient treatment	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 1st March 2017 11th January 2017	24th January 2017
			Routinely available in line with local guidance 1st March 2017	15th March 2017

799/12 7th December 2012	Dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®)	Use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: Add-on combination therapy In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** Dapagliflozin is restricted to use as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate.	**Include** Specialist consultant initiation 6th February 2013	20th February 2013
799/12 resub 7th February 2014	Dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®)	Use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** In combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control.	**Include** Consultant initiation 12th March 2014	24th March 2014
799/12 resub 6th June 2014	Dapagliflozin 5mg and 10mg film-coated tablet (Forxiga®)	In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** in triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor.	**Include** Consultant initiation First choice within therapeutic class 13th August 2014	22nd August 2014
983/14 4th July 2014	Dapagliflozin plus metformin 5mg/850mg and 5mg/1000mg film-coated tablets (Xigduo®)	in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: • in patients inadequately controlled on their maximally tolerated dose of metformin alone; • in combination with other glucose-lowering medicinal products, including insulin, in patients inadequately controlled with metformin and these medicinal products; • in patients already being treated with the combination of dapagliflozin and metformin as separate tablets. **SMC restriction:** to use in patients for whom a combination of dapagliflozin and metformin is an appropriate choice of therapy i.e. • when metformin alone does not provide adequate glycaemic control and a sulphonylurea is inappropriate. • in combination with insulin, when insulin and metformin does	**Include** Consultant initiation, as per SMC restrictions 13th August 2014	22nd August 2014

		not provide adequate control. • in combination with a sulphonylurea, when a sulphonylurea and metformin does not provide adequate control.		
1205/17 resubmission 9th October 2017	Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®)	As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. **SMC restriction:** for use as a fourth line treatment option	Routinely available in line with local guidance 4th October 2017	13th October 2017
861/13 8th March 2013	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 as well as antiretroviral therapy-experienced paediatric patients from the age of 3 years and at least 15 kg body weight. **SMC restriction:** to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV.	**Include** Specialist consultant initiation 1st May 2013	13th May 2013
948/14 7th February 2014	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 and at least 40kg body weight who are: antiretroviral therapy (ART) naïve; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm^3. **SMC restriction:** in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV.	**Include** Specialist Consultant initiation 7th May 2014	19th May 2014
1069/15 5th June 2015	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 >100x106 cells/L. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric HIV.	**Include** Specialist consultant initiation 27th August 2015	1st September 2015
1081/15 10th July 2015	Darunavir 800mg, cobicistat 150mg film-coated tablet (Rezolsta®)	In combination with other antiretroviral medicinal products for the treatment of human immuno-deficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd September 2015	14th September 2015
SMC 1290/18	Darunavir 800mg, cobicistat	Treatment of human immunodeficiency virus type 1 (HIV-1)	Not routinely available as local clinical	24th January

8th December 2017	150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®)	infection in adults and adolescents (aged 12 years and older with body weight at least 40kg	experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Joint Formulary) 10th January 2018	2018
1170/16 5th August 2016	Dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®)	Treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th November 2016 7th September 2016	20th September 2016
			Available in line with local guidance for prescribing 10th October 2016	18th October 2016
370/07 resubmission 5th August 2016	Dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®)	Treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th November 2016 7th September 2016	20th September 2016
			Available in line with local guidance for prescribing 10th October 2016	18th October 2016
967/14 9th May 2014	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.	**Include** Specialist initiation 7th July 2014	24th October 2014
1194/16 7th October 2016	Dequalinium chloride 10mg vaginal tablets (Fluomizin®)	Treatment of bacterial vaginosis. **SMC restriction:** In patients for whom the initial treatment is not effective or well tolerated.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 11th January 2016 2nd November 2016	16th November 2016
			Available in line with local guidance for prescribing 7th December 2016	19th December 2016

347/07 resubmission 9th December 2016	Deferasirox 125mg, 250mg, 500mg dispersible tablets (Exjade®)	Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias. The current advice relates only to use in the myelodysplastic syndrome (MDS) population. **SMC restriction:** use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate - 1 risk	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 11th January 2017	24th January 2017
			Routinely available in line with local guidance 6th February 2017	15th February 2017
1246/17 5th May 2017	Deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®)	• Treatment of chronic iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. • Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups: ○ in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) aged 2 to 5 years, ○ in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7mL/kg/month of packed red blood cells) aged 2 years and older, ○ in adult and paediatric patients with other anaemias aged 2 years and older. **SMC restriction:** deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07).	Routinely available in line with local guidance 7th June 2017	21st June 2017
1218/17 resubmission 7th July 2017	Desmopressin 25 microgram, 50 microgram oral lyophilisate (Noqdirna®)	Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. **SMC restriction:** For use in patients aged 65 years and over.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 4th October 2017 22nd August 2017	23rd August 2017
			Routinely available in line with local guidance 6th December 2017	21st December 2017

652/10 resubmission 4th May 2012	Dexamethasone 700 microgram intravitreal implant (Ozurdex®)	Treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion. **SMC restriction:** for use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment.	**Include** Pending protocol 2nd July 2012	18th July 2012
1046/15 10th April 2015	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.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 3rd June 2015	15th June 2015
784/12 4th May 2012	Dexmedetomidine 100 micrograms/mL concentrate for solution for infusion (Dexdor®)	Sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3).	**Exclude** Pending protocol (Joint Formulary) 2nd July 2012	18th July 2012
1172/16 8th July 2016	Diamorphine hydrochloride 720 microgram/actuation and 1600 microgram/actuation nasal spray (Ayendi®)	Treatment of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray (Ayendi®) should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th October 2016 10th August 2016	15th August 2016
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance) 2nd November 2016	16th November 2016
886/13 7th March 2014	Dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®)	Treatment of adult patients with relapsing remitting multiple sclerosis.	**Include** Consultant initiation Case by case form requires to be completed before treatment initiation 5th May 2014	19th May 2014
961/14	Dolutegravir 50mg film-coated tablets (Tivicay®)	In combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected	**Include**	17th June 2014

4th April 2014		adults and adolescents above 12 years of age.	Pending protocol Case by case form requires to be completed before treatment initiation 4th June 2014	
1009/14 7th November 2014	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 40 kg.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 3rd December 2014	17th December 2014
1253/17 9th June 2017	Dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®)	In combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged >6 to 12 years of age.	Routinely available from a specialist centre in another health board 9th August 2017	23rd August 2017
1110/15 4th December 2015	Dulaglutide 0.75mg and 1.5mg solution for injection in pre-filled pen (Trulicity®)	In adults with type 2 diabetes mellitus to improve glycaemic control as add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** as part of a triple therapy in patients with inadequate glycaemic control on two oral anti-diabetic drugs, as an alternative glucagon-like peptide 1 (GLP-1) agonist option.	**Exclude** Pending protocol (Joint Formulary) 2nd March 2016	16th March 2016
1090/15 9th October 2015	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.	**Exclude** Pending protocol (Joint Formulary) 6th January 2016	20th January 2016
1095/15 9th October 2015	Edoxaban tosilate15mg, 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, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).	**Exclude** Pending protocol (Joint Formulary) 6th January 2016	20th January 2016
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance) 7th March 2016	18th May 2016
1125/15 6th November 2015	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.	**Include** Specialist consultant initiation 6th January 2016	20th January 2016

1203/17 9th December 2016	Elbasvir 50 mg, grazoprevir 100mg film-coated tablet (Zepatier®)	Treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 11th January 2017	24th January 2017
			Routinely available in line with national guidance 6th February 2017	15th February 2017
SMC 1277/17	Eliglustat 84mg hard capsules (Cerdelga®)	Long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolisers, intermediate metabolisers or extensive metabolisers	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th February 2018 6th December 2017	21st December 2017
919/13 8th November 2013	Eltrombopag, 25mg, 50mg, 75mg film-coated tablets (Revolade®)	In adult patients with 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	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 13th January 2014	22nd January 2014
1206/17 9th December 2016	Eltrombopag (Revolade®) film-coated tablets 25mg and 50mg	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to 17 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). **SMC restriction:** use in patients with severe symptomatic ITP or a high risk of bleeding	Routinely available from a specialist centre in another health board 11th January 2017	24th January 2017
887/13 5th July 2013	Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg film coated tablet (Stribild®)	Treatment of human immunodeficiency virus-1 (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®.	**Include** Pending protocol 4th September 2013	18th September 2013
1142/16 8th April 2016	Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Genvoya®)	Treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 29th August 2016	12th May 2016

			4th May 2016	
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
993/14 5th September 2014	Empagliflozin 10mg and 25mg tablet (Jardiance®)	Treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy: in combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction**: to use in the following situations: • dual therapy in combination with metformin, when a sulphonylurea is inappropriate • triple therapy in combination with metformin plus standard of care • add-on to insulin therapy in combination with insulin plus standard of care	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 10th October 2014	24th October 2014
1092/15 4th September 2015	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; • in patients inadequately controlled on their maximally tolerated dose of metformin alone • in patients inadequately controlled with metformin in combination with other glucose-lowering medicinal products, including insulin in patients already being treated with the combination of empagliflozin and metformin as separate tablets.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary) 7th October 2015	20th October 2015
1169/16 8th July 2016	Emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film-coated tablets (Descovy®)	In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th October 2016 10th August 2016	15th August 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
1225/17 10th March 2017	Emtricitabine/ tenofovir disoproxil 200mg/ 245mg film-coated tablets	In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical	19th April 2017

	(Truvada®)		experts – decision expected by 5th June 2017 5th April 2017	
			Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 4th September 2017 8th May 2017	22nd May 2017
			Routinely available in line with national guidance 11th August 2017	23rd August 2017
1049/15 10th April 2015	Entecavir,0.5 and 1mg film-coated tablets and 0.05mg/mL oral solution (Baraclude®)	Treatment of chronic hepatitis B virus infection in nucleoside naive paediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum alanine aminotransferase levels, or histological evidence of moderate to severe inflammation and/or fibrosis. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric infectious diseases.	**Include** Specialist consultant initiation 3rd June 2015	15th June 2015
911/13 4th October 2013	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	**Include** Pending West of Scotland Cancer Network protocol Case by case form requires to be completed before treatment initiation 11th November 2013	18th November 2013
			Include Consultant initiation as per West of Scotland Cancer Network protocol Case by case form must be completed before prescribing can be initiated 12th March 2014	24th March 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015

1066/15 resubmission 5th February 2016	Enzalutamide 40mg soft capsules (Xtandi®)	Treatment of men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated (	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 20th June 2016 28th April 2016	12th May 2016
			Available in line with local guidance for prescribing 29th August 2016	20th September 2016
793/12 8th June 2012	Eplerenone 25, 50mg film-coated tablets (Inspra®)	In addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%).	**Include** Consultant initiation 4th July 2012	18th July 2012
1065/15 resubmission 5th February 2016	Eribulin (mesilate), 0.44mg/mL solution for injection (Halaven®)	Treatment of adults with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. **SMC restriction:** use in patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 20th June 2016 28th April 2016	12th May 2016
			Routinely available in line with local guidance	15th March 2017
781/12 5th April 2012	Etanercept 10mg and 25mg powder and sterile water for solution for injection for paediatric use(Enbrel®)	Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. **SMC restriction:** - the disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10; - the psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments; - etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 2nd May 2012	16th May 2012

782/12 5th April 2012	Etanercept 10mg and 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®)	Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. **SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology)	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 2nd May 2012	16th May 2012
842/13 11th January 2013	Etanercept 10mg and 25mg powder and solvent for solution for injection for paediatric use, 25mg and 50mg solution for injection in pre-filled syringe, 50mg solution for injection in pre-filled pen (Enbrel®)	For the treatment of • polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; • psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate; • enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy. **SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology).	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 6th March 2013	15th March 2013
901/13 9th August 2013	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 from 6 years to less than 18 years of age. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric HIV.	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
777/12 5th April 2012	Everolimus, 5mg, 10mg tablets (Afinitor®)	Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease	**Include** Specialist consultant initiation Case by case form must be completed before prescribing can be initiated 11th June 2012	20th June 2012
595/10 resub 10th October 2014	Everolimus 2.5mg, 5mg 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.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 15th December 2014	17th December 2014
872/13	Everolimus 2.5mg, 5mg and	Treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in	Not routinely available as local implementation plans are being	12th May 2016

resubmission 4th March 2016	10mg tablets (Afinitor®)	postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor	developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 29th August 2016 9th May 2016	
			Routinely available in line with local guidance 6th September 2017	20th September 2017
1215/17 13th January 2017	Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®)	Treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 6th February 2017	15th February 2017
			Routinely available from a specialist centre in another health board 6th March 2017	15th March 2017
1148/16 resubmission 13th January 2017	Evolocumab 140mg solution for injection in pre-filled pen (Repatha® Sureclick) or pre-filled syringe (Repatha® PFS)	In adults with primary hyper-cholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or, • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. **SMC restriction:** for specialist use only, when administered at a dose of 140mg every two weeks, in patients at high cardiovascular risk as follows: • patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L for primary prevention of cardiovascular events or, • patients with HeFH and LDL-C ≥3.5mmol/L for secondary prevention of cardiovascular events or, • patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L or • patients with recurrent/polyvascular disease and LDL-C	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 6th February 2017	15th February 2017
			Routinely available in line with local guidance 6th March 2017	15th March 2017

		≥3.5mmol/L		
785/12 4th May 2012	Exenatide, 5 micrograms & 10 micrograms, solution for injection, prefilled pen (Byetta®)	As adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults with type 2 diabetes who have not achieved adequate glycaemic control with these agents.	**Include** Consultant diabetologist initiation 4th July 2012	18th July 2012
1153/16 6th May 2016	Febuxostat 120mg film-coated tablet (Adenuric®)	Prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS).**SMC restriction**: prevention of hyperuricaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated, such as: • Those intolerant of allopurinol • Those in whom allopurinol is contraindicated, e.g. patients with renal impairment	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th September 2016 1st June 2016	15th June 2016
			Available in line with local guidance for prescribing 10th August 2016	15th August 2016
833/13 11th January 2013	Ferumoxytol, 30mg/mL solution for injection (Rienso®)	Intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease. **SMC restriction:** treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary) 6th March 2013	15th March 2013
791/12 8th June 2012	Fidaxomicin 200mg film-coated tablets (Dificlir®)	Treatment of adults with *Clostridium difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD). **SMC restriction:** Treatment of adults with a first CDI recurrence only on the advice of local microbiologists or specialists in infectious diseases.	**Include** Consultant initiation (microbiologists or specialist in infectious diseases) for treatment of adults with first CDI recurrence 3rd September 2012	13th September 2012
763/12 (resub) 10th August 2012	Fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®)	As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: • Patients with high disease activity despite treatment with a beta-interferon. These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least one relapse in the previous year while on therapy, and have at least nine T2-hyperintense lesions in cranial magnetic resonance imaging	**Include** Specialist consultant initiation Case by case form must be completed before prescribing can be initiated 1st October 2012	11th October 2012

		(MRI) or at least one gadolinium-enhancing lesion. A "non-responder" could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. or • Patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. **SMC restriction:** restricted to use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.		
992/14 8th August 2014	Fingolimod, 0.5mg, hard capsules (Gilenya®)	As a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups: - Patients with high disease activity despite treatment with at least one disease modifying therapy. or - Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. **SMC restriction:** For use in patients with rapidly evolving severe relapsing remitting multiple sclerosis. SMC has previously published advice concerning patients with high disease activity despite treatment with beta-interferon.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 20th October 2014	24th October 2014
1038/15 6th March 2015	Fingolimod 0.5mg hard capsules (Gilenya®)	as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: • Patients with high disease activity despite treatment with at least one disease modifying therapy.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 11th May 2015	20th May 2015
864/13 resub 10th January 2014	Fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®)	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. **SMC restriction:** • only in patients in whom the affected eye is pseudophakic	**Include** Pending protocol Case by case form requires to be completed before treatment initiation	24th March 2014

		(has an artificial lens after cataract surgery) and; • retreatment would take place only if the patient had previously responded to treatment with fluocinolone acetonide and subsequently best corrected visual acuity had deteriorated to less than 20/32.	12th March 2014	
953/14 7th March 2014	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. **SMC restriction:** in patients with severe COPD (FEV1 <50% predicted normal).	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 4th June 2014	17th June 2014
			Include 2nd choice within therapeutic class 27th August 2015	1st September 2015
966/14 9th May 2014	Fluticasone furoate / vilanterol 92/22, 184/22 micrograms inhalation powder (Relvar Ellipta®)	The regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 4th June 2014	17th June 2014
			Include 1st Choice within therapeutic class 27th August 2015	1st September 2015
736/11 7th September 2012	Fluticasone proprionate and formoterol fumarate metered dose inhaler, 50microgram/5microgram, 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 β2 agonist (LABA)] is appropriate: • for patients not adequately controlled on ICS and 'as required' inhaled short-acting β2 agonist or • for patients already adequately controlled on both an ICS and a LABA.	**Include** 7th November 2012	19th November 2012
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance guidance) 8th May 2017	22nd May 2017
1025/15 9th January 2015	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) in women who have been unresponsive to treatment with clomiphene citrate. • stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive	**Exclude** Clinicians do not support formulary inclusion (Joint Formulary) 1st April 2015	14th April 2015

		technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer. • in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and follicle-stimulating hormone (FSH) deficiency. In clinical trials these patients were defined by an endogenous serum LH level <1.2 units/L. In adult men for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human chorionic gonadotrophin (hCG) therapy. Follitropin alfa (Bemfola®) is a biosimilar that has demonstrated clinical equivalence to another follitropin alfa product for stimulation of multi-follicular development for superovulation in ART. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.		
1033/15 6th February 2015	Fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt®)	Treatment of the following infections in adults and children including neonates: - Acute osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above Fosfomycin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections listed above, or when these alternative antibacterial agents have failed to demonstrate efficacy. Consideration should be given to national guidance on the appropriate use of antibacterial agents. **SMC restriction:** initiation by microbiologists or infectious disease specialists.	**Include** Specialist consultant initiation as per SMC restrictions 1st April 2015	14th April 2015
1163/16 5th August 2016	Fosfomycin trometamol granules for oral solution (equivalent to 3g fosfomycin) (Monuril®)	• Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. • Prophylaxis in diagnostic and surgical transurethral	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2nd	20th September 2016

		procedures.	November 2016 7th September 2016	
			Available in line with local guidance for prescribing 2nd November 2016	16th November 2016
114/04 resub 8th January 2016	Fulvestrant, 250mg, solution for injection (Faslodex®)	Treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
			Routinely available in line with local guidance 6th March 2017	15th March 2017
615/10 resub 6th November 2015	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). **SMC restriction:** in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
			Available in line with local guidance for prescribing 9th May 2016	12th May 2016
			Not routinely available as local clinical experts do not wish to add the medicine to formulary at this time or there is a local preference for alternative medicines (link to local guidance) 29th August 2016	20th September 2016
1108/15 6th November 2015	Glatiramer acetate 40mg/mL solution for injection prefilled syringes (Copaxone®)	Treatment of relapsing forms of multiple sclerosis (MS).	**Include** Consultant initiation 6th January 2016	20th January 2016
1278/17 6th October 2017	Glecaprevir 100mg, pibrentasvir 40mg film-coated tablet (Maviret®)	Treatment of chronic hepatitis C virus (HCV) infection in adults.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th	22nd November 2017

			December 2017 1st November 2017	
			Routinely available in line with national guidance NHS Scotland Hepatitis C guidance	6th December 2017
829/12 7th December 2012	Glycopyrronium 44 micrograms hard capsules of inhalation powder (Seebri Breezhaler®)	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)	**Include** 6th February 2013	20th February 2013
			Exclude Clinicians do not support the formulary inclusion (Joint Formulary) 27th August 2015	1st September 2015
1254/17 9th June 2017	Glycopyrronium 320 micrograms/mL (glycopyrronium bromide 400 micrograms/mL) oral solution (Sialanar®)	Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th September 2017 9th August 2017	23rd August 2017
			Routinely available in line with local guidance 1st November 2017	22nd November 2017
674/11 (resub) 8th June 2012	Golimumab, 50mg, solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (Simponi®)	Alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **SMC restriction:** golimumab is restricted to use in patients whose disease has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is also restricted to use at a dose of 50mg only.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 4th July 2012	18th July 2012
1124/16 8th January 2016	Golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®)	Treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
895/13 6th September	Granisetron 3.1mg / 24 hours transdermal patch	In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a	**Include** Specialist initiation	18th November 2013

2013	(Sancuso®)	planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult	6th November 2013	
1123/16 8th January 2016	Guanfacine, 1mg, 2mg, 3mg and 4mg prolonged-release tablets (Intuniv®)	Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.	**Include** Consultant initiation 2nd March 2016	16th March 2016
1150/16 8th July 2016	Ibrutinib 140mg hard capsule (Imbruvica®)	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 10th October 2016 1st August 2016	15th August 2016
			Available in line with local guidance for prescribing 10th October 2016	18th October 2016
1151/16 8th July 2016	Ibrutinib 140mg hard capsules (Imbruvica®)	Treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. **SMC restriction:** patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 10th October 2016 1st August 2016	15th August 2016
			Available in line with local guidance for prescribing 10th October 2016	18th October 2016
1151/16 resubmission 10th March 2017	Ibrutinib 140mg hard capsules (Imbruvica®)	Treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. **SMC restriction:** patients with relapsed/refractory CLL and for whom fludarabine-based regimens are inappropriate.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th June 2017 5th April 2017	19th April 2017
			Routinely available in line with local guidance 8th May 2017	22nd may 2017

1178/16 5th August 2016	Idarucizumab 2.5g/50mL solution for injection/infusion (Praxbind®)	Idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.	Available in line with local guidance for prescribing 7th September 2016	20th September 2016
1226/17 7th April 2017	Idebenone (Raxone®) 150mg film-coated tablets	Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). **SMC restriction:** to patients with LHON who are not yet blind i.e. they do not meet the UK criteria to be registered as severely sight impaired.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th August 2017 8th May 2017	22nd may 2017
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Joint Formulary) 10th January 2018	24th January 2018
1026/15 6th February 2015	Idelalisib 100mg and 150mg tablets (Zydelig®)	In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • who have received at least one prior therapy, or • as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. **SMC restriction:** patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd March 2015	16th March 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1039/15 10th April 2015	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.	**Include** Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
922/13 7th November 2014	Indacaterol maleate 143micrograms (equivalent to 110microgram indacaterol) with glycopyrronium bromide 63micrograms (equivalent to 50microgram glycopyrronium) inhalation	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	**Exclude** Pending protocol (Joint Formulary) 4th February 2015	16th February 2015
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time	22nd May 2017

	powder hard capsules (Ultibro® Breezhaler® 85microgram/43microgram [delivered dose])		or there is a local preference for alternative medicines (local guidance guidance) 8th May 2017	
854/13 8th February 2013	Infliximab 100mg powder for concentrate for solution for infusion (Remicade®)	Treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies. **SMC restriction:** as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 1st May 2013	13th May 2013
1006/14 6th March 2015	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 in: • adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; • adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. Infliximab (Remsima®) is also indicated in the following conditions: adult and paediatric Crohn's disease and ulcerative colitis; adult psoriatic arthritis, psoriasis and ankylosing spondylitis. **SMC restriction:** Infliximab (Remsima®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®].	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 3rd June 2015	15th June 2015
1007/14 6th March 2015	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 in: • adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; • adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. Infliximab (Inflectra®) is also indicated in the following conditions: adult and paediatric Crohn's disease and ulcerative colitis; adult ankylosing spondylitis, psoriatic arthritis and psoriasis.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 3rd June 2015	15th June 2015
			Exclude Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary)	1st September 2015

		SMC restriction: Infliximab (Inflectra®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®].	27th August 2015	
851/13 8th February 2013	Ingenol mebutate, 150 & 500micrograms/g, gel (Picato®)	Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.	**Include** Specialist initiation 3rd April 2013	17th April 2013
1227/17 10th March 2017	Insulin aspart (Fiasp®) 100 units/mL solution for injection in vial; solution for injection in cartridge (Penfill®); solution for injection in pre-filled pen (FlexTouch®)	Treatment of diabetes mellitus in adults.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th June 2017 5th April 2017	19th April 2017
			Routinely available in line with local guidance 7th June 2017	21st june 2017
856/13 resubmission 8th July 2016	Insulin degludec (Tresiba®) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen	Treatment of diabetes mellitus in adults.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th October 2016 10th August 2016	15th August 2016
			Available in line with local guidance for prescribing 2nd November 2016	16th November 2016
1088/15 4th September 2015	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 when these alone or combined with a GLP-1 receptor agonist or with basal insulin do not provide adequate glycaemic control	**Include** Consultant initiation, pending protocol 2nd December 2015	16th December 2015
780/12 5th April 2012	Insulin detemir (Levemir®)	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. **SMC restriction**: in patients unable to achieve good glycaemic control with established insulins	**Include** Paediatrician initiation, as per local guidelines 2nd May 2012	16th May 2012
1126/16	Insulin detemir 100units/mL, solution for injection in	Treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. **SMC restriction:** in patients	**Include** Consultant initiation	16th March 2016

	cartridge (Penfill), pre- filled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®)	unable to achieve good glycaemic control with established insulins	2nd March 2016	
860/13 8th March 2013	Insulin glargine 100units/ml solution for injection in a vial, cartridge, pre-filled pen (Lantus®, Clikstar®, Lantus® Solostar®)	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. **SMC restriction:** patients in whom treatment with an insulin analogue is appropriate.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) *Insulin glargine remains on formulary for children from aged 6 years and adults as per SMC restrictions/ local guidelines* 1st May 2013	13th May 2013
1078/15 7th August 2015	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. **SMC restriction:** Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections.	**Include** Consultant initiation 4th November 2015	16th November 2015
779/12 resub 8th March 2013	Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated in the interim 29th April 2013	13th May 2013
			Include Specialist consultant initiation as per West of Scotland cancer Network protocol 12th August 2013	26th August 2013
997/14 10th October 2014	Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use).	**Include** Pending protocol Case by case form requires to be completed before treatment initiation	17th December 2014

			15th December 2014	
1177/16 resubmission 13th January 2017	Iron III isomaltoside 1000 (contains 50mg iron per mL) (Diafer®), solution for injection	Treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th April 2017 1st February 2017	15th February 2017
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance) 5th April 2017	19th April 2017
805/12 7th September 2012	Ivabradine 5 and 7.5mg film-coated tablets (Procoralan®)	Chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 beats per minute (bpm), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated. **SMC restriction:** for initiation only in patients whose resting heart rate remains ≥75 beats per minute despite optimal standard therapy	**Include** Specialist recommendation 7th November 2012	19th November 2012
1129/16 4th March 2016	Isavuconazole, 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®)	In adults for the treatment of: • invasive aspergillosis • mucormycosis in patients for whom amphotericin B is inappropriate	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance) 6th June 2016	15th June 2016
1104/15 6th November 2015	Ivermectin, 10mg/g, cream (Soolantra®)	Topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients. **SMC restriction:** the treatment of moderate to severe inflammatory lesions of rosacea where a topical treatment is considered appropriate.	**Include** 3rd February 2016	11th February 2016
1223/17 10th March 2017	Ixekizumab 80mg solution for injection (Taltz®)	Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th June 2017 5th April 2017	19th April 2017

			Routinely available in line with local guidance 8th May 2017	22nd May 2017
821/12 9th November 2012	Lanthanum carbonate 750mg and 1000mg oral powder (Fosrenol®)	As a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Lanthanum is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels 1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels. **SMC restriction:** as a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required.	**Include** Specialist consultant initiation 5th December 2012	17th December 2012
879/13 7th June 2013	Latanoprost preservative-free single-dose eye-drops (Monopost®) - open angle glaucoma and ocular hypertension	Reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. **SMC restriction:** to use in patients who have proven sensitivity to the preservative benzalkonium chloride.	**Include** Specialist initiation as per SMC restrictions 14th August 2013	26th August 2013
1030/15 6th February 2015	Ledipasvir/sofosbuvir, 90mg/400mg, film-coated tablet (Harvoni®)	Treatment of chronic hepatitis C (CHC) in adults. **SMC restriction:** genotype 1 and 4 CHC only.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd March 2015	16th March 2015
			Routinely available in line with national guidance (NHS Scotland Hepatitis C January 2017 guidelines) 6th March 2017	15th March 2017
1084/15 7th August 2015	Ledipasvir/sofosbuvir 90mg/400mg film-coated tablet (Harvoni®)	Treatment of genotype 3 chronic hepatitis C (CHC) in adults. **SMC restriction:** patients who are ineligible for or unable to tolerate interferon.	**Include** As per national protocol 7th September 2015	14th September 2015
942/14 7th February 2014	Lenalidomide 2.5mg, 5mg, and 10mg, hard capsules (Revlimid®)	Treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation	10th April 2014

			7th April 2014	
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
441/08 resub 7th March 2014	Lenalidomide, 5mg, 10mg, 15mg and 25mg hard capsules (Revlimid®)	In combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy). **SMC restriction:** to use at first relapse in patients who have received prior therapy with bortezomib in whom thalidomide has not been tolerated or is contraindicated.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 5th May 2014	19th May 2014
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1096/15 6th November 2015	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. **SMC restriction**: for use in patients unsuitable for thalidomide-containing regimens	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
1179/16 9th September 2016	Lenvatinib 4mg and 10mg hard capsules (Lenvima®)	Treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).	Available from a specialist centre in another NHS board 10th October 2016	18th October 2016
1162/16 8th July 2016	Levofloxacin 240mg nebuliser solution (Quinsair®)	Management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis. **SMC restriction:** for use as a third line treatment option after colistimethate sodium (first line) and tobramycin (second line).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th September 2016 10th August 2016	15th August 2016
			Available in line with local guidance for prescribing 7th September 2016	20th September 2016

938/14 10th January 2014	Levonorgestrel 1500microgram tablet (Upostelle®)	Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.	**Include** 12th March 2014	24th March 2014
1036/15 6th March 2015	Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®)	Contraception for up to 3 years.	**Include** Second choice 3rd June 2015	15th June 2015
1058/15 8th May 2015	Levonorgestrel (Levosert®) 20 micrograms/24 hours intrauterine delivery system	Contraception. Heavy menstrual bleeding.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 3rd June 2015	15th June 2015
869/13 10th May 2013	Linaclotide hard capsules, 290 micrograms (Constella®)	Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation in adults	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 5th June 2013	17th June 2013
850/13 11th January 2013	Linagliptin, 5mg film-coated tablets (Trajenta®)	Treatment of type 2 diabetes mellitus to improve glycaemic control in adults: - **As monotherapy:** • in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment. - **As combination therapy**: • in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products does not provide adequate glycaemic control. • in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. **SMC restriction:** • as monotherapy in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance. • as combination therapy with a sulphonylurea and metformin when diet and exercise plus dual therapy does not provide adequate glycaemic control.	**Include** As per SMC restrictions 2nd choice formulary DPP-4 inhibitor 3rd April 2013	17th April 2013
850/13 resub 10th April 2015	Linagliptin 5mg tablet (Trajenta®)	Treatment of type 2 diabetes mellitus to improve glycaemic control in adults in combination with insulin with or without metformin, when this regimen alone, with diet and exercise,	**Include** Second choice within therapeutic class	20th May 2015

		does not provide adequate glycaemic control.	6th May 2015	
841/13 11th January 2013	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: • as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin. • in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylureas **SMC restriction**: to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and these fixed- doses are considered appropriate.	**Include** As per SMC restrictions 2nd choice formulary DPP-4 inhibitor 3rd April 2013	17th April 2013
1057/15 8th May 2015	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 (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide adequate glycaemic control. **SMC restriction:** to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and the fixed doses are considered appropriate.	**Include** Second choice within therapeutic class**,** as per SMC restrictions 3rd June 2015	15th June 2015
908/13 7th March 2014	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 (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). **SMC restriction:** where a long-acting granulocyte-colony-stimulating factor is appropriate.	**Include** Consultant initiation as per West of Scotland Cancer Network protocol 7th May 2014	19th May 2014
1044/15 10th April 2015	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.	**Include** Consultant initiation Second choice within therapeutic class 6th May 2015	20th May 2015
863/13 5th April 2013	Lisdexamfetamine dimesylate, 30mg, 50mg & 70mg capsules (Elvanse®)	As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate	**Include** Specialist consultant initiation 5th June 2013	17th June 2013
1079/15 7th August 2015	Lisdexamfetamine dimesylate, 30mg, 50mg and 70mg hard capsules	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	**Include** Pending protocol 4th November 2015	16th November 2015

	(Elvanse Adult®)	severity.		
903/13 9th August 2013	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 when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** to use in patients for whom a glucagon-like protein-1 (GLP-1) agonist is appropriate, as an alternative to existing GLP-1 agonists.	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
994/14 5th September 2014	Lurasidone, 18.5mg, 37mg, 74mg film-coated tablets (Latuda®)	Treatment of schizophrenia in adults aged 18 years and over. **SMC Restriction:** as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects.	**Include** Specialist initiation 5th November 2014	19th November 2014
952/14 7th March 2014	Macitentan 10mg film-coated tablets (Opsumit®)	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. **SMC restriction:** to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or similar specialists.	**Include** Specialist initiation 5th May 2014	19th May 2014
1042/15 5th June 2015	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	**Include** 27th August 2015	1st September 2015
1267/17 11th September 2017	Magnesium glycerophosphate 4mmol chewable tablet (Neomag®)	As an oral magnesium supplement for the treatment of patients with chronic magnesium loss or hypomagnesaemia as diagnosed by a doctor. Magnesium glycerophosphate is also indicated for adult patients with hypomagnesaemia due to the concomitant administration of loop and thiazide diuretics or other drugs which cause hypomagnesaemia	Routinely available in line with national guidance 6th September 2017	20th September 2017
837/13 resub 8th November 2013	Mannitol 40mg inhalation powder hard capsule (Bronchitol®)	Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. **SMC restriction:** As an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining lung function and in whom other osmotic agents are considered unsuitable.	**Include** Specialist initiation as per SMC restrictions 8th January 2014	22nd January 2014
896/13 9th August 2013	Medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana®	Long-term female contraception	**Include** 2nd October 2013	16th October 2013

	Press)			
1149/16 6th May 2016	Mepolizumab 100mg powder for solution for injection (Nucala®)	As an add-on treatment for severe refractory eosinophilic asthma in adult patients.**SMC restriction:** patients who have eosinophils of at least 150 cells per microlitre (0.15 x 10^9/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th September 2016 6th June 2016	15th June 2016
			Available in line with local guidance for prescribing 1st August 2016	15th August 2016
798/12 6th July 2012	Mercaptopurine 20mg/mL oral suspension (Xaluprine®)	Treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children	**Include** Specialist consultant initiation 5th September 2012	13th September 2012
1094/15 4th September 2015	Midodrine hydrochloride (Bramox®) 2.5mg, 5mg tablets	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	**Include** Specialist initiation 4th November 2015	16th November 2015
SMC 935/13 7th April 2017	Micronised progesterone vaginal capsules 200mg (Utrogestan Vaginal®)	In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th July 2017 3rd May 2017	22nd May 2017
935/13 5th May 2017	Micronised progesterone vaginal capsules 200mg (Utrogestan Vaginal®)	In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.	Routinely available from a specialist centre in another health board 7th June 2017	21st June 2017
1279/19 6th October 2017	Midazolam (as maleate) 10mg/1mL oromucosal solution prefilled syringe (Epistatus® PFS)	Treatment of prolonged, acute, convulsive seizures in children and adolescents aged 10 to less than 18 years.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 10th January 2018 1st November 2017	22nd November 2017
			Routinely available in line with local guidance 10th January 2018	24th January 2018

913/13 10th October 2014	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.	**Include** Specialist initiation/ hospital use only 3rd December 2014	17th December 2014
1196/16 7th October 2016	Migalastat, 123mg hard capsules (Galafold®)	Long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation. **SMC restriction:** in males with classic mutations (leucocyte enzyme activity <1%) treatment should commence at diagnosis; in females and those males with later onset mutations with higher levels of leucocyte enzyme activity, treatment should commence when patients experience uncontrolled pain, evidence of renal, cardiac or neurovascular disease, or gastrointestinal symptoms that significantly reduce quality of life.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th January 2017 7th November 2016	16th November 2016
			Available from a specialist centre in another NHS board 5th December 2016	19th December 2016
862/13 5th April 2013	Mirabegron 25mg and 50mg prolonged-release tablets (Betmiga®)	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder syndrome	**Include** Specialist initiation 5th June 2013	17th June 2013
996/14 5th September 2014	Misoprostol, 200 microgram, vaginal delivery system (Mysodelle®)	Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 10th October 2014	24th October 2014
917/13 6th September 2013	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	**Include** Pending protocol 4th November 2013	18th November 2013
1106/15 6th November 2015	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).	**Include** 6th January 2016	20th January 2016
1154/16 6th May 2016	Naproxen 250mg effervescent tablets (Stirlescent®)	Treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults.**SMC restriction:** use in patients unable to swallow naproxen tablets	Available in line with national guidance 1st June 2016	15th June 2016
813/12 5th October 2012	Nepafenac 1mg/mL eye drops, suspension (Nevanac®)	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients	**Include** Ophthalmology initiation 5th December 2012	17th December 2012

SMC 1228/17 7th April 2017	Nepafenac 3mg/mL eye drops, suspension (Nevanac®)	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th July 2017 3rd May 2017	22nd May 2017
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance) 7th June 2017	21st June 2017
1109/15 4th December 2015	Netupitant/palonosetron 300mg/0.5mg, hard 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. **SMC restriction:** prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary (Joint Formulary) 2nd March 2016	16th March 2016
1027/15 6th March 2015	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.	**Include** Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1076/15 4th September 2015	Nintedanib 100mg and 150mg capsules (Ofev®)	In adults for the treatment of idiopathic pulmonary fibrosis (IPF) **SMC restriction:** For use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd November 2015	16th November 2015
1120/16 resubmission 8th July 2016	Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®)	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. **SMC restriction:** patients previously untreated with ipilimumab.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 10th October 2016 1st August 2016	15th August 2016

			Available from a specialist centre in another NHS board 10th October 2016	18th October 2016
1144/16 10th June 2016	Nivolumab 40mg/4mL and 100mg/10mL vials of concentrate for solution for infusion (Opdivo®)	Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2nd November 2016 1st August 2016	15th August 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
1180/16 9th September 2016	Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®)	Treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. **SMC restriction:** treatment with nivolumab is subject to a two-year clinical stopping rule.	Available in line with local guidance for prescribing 10th October 2016	18th October 2016
1187/16 7th October 2016	Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	In combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults. **SMC restriction:** for the first-line treatment of advanced melanoma	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th January 2017 7th November 2016	16th November 2016
			Available from a specialist centre in another NHS board 5th December 2016	19th December 2016
1188/16 resubmission 5th May 2017	Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®)	As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults.	Routinely available from a specialist centre in another health board 20th June 2017	21st June 2017
1240/17 9th June 2017	Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	Treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.	Routinely available in line with local guidance 10th August 2017	23rd August 2017
1261/17 11th September 2017	Nivolumab, 10mg/mL concentrate for solution for infusion (Opdivo®)	As monotherapy, for the treatment of squamous cell cancer of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy. **SMC restriction:** treatment with nivolumab is subject to a two year clinical stopping rule.	Routinely available from a specialist centre in another health board 13th September 2017	20th September 2017

1232/17 5th May 2017	Obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva®)	Primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 4th September 2017 20th June 2017	21st June 2017
			Routinely available in line with local guidance 10th August 2017	23rd August 2017
1008/14 7th November 2014	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 (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd February 2015	16th February 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1219/17 10th February 2017	Obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®)	Obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen	Routinely available in line with local guidance 6th March 2017	15th March 2017
892/13 resub 4th July 2014	Ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®)	In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. **SMC restriction:** patients with vitreomacular traction plus macular hole, regardless of whether they have epiretinal membrane formation, and in patients with vitreomacular traction alone (no epiretinal membrane and no macular hole).	**Exclude** Pending protocol Case by case form requires to be completed before treatment initiation 1st September 2014	10th October 2014
1037/15 10th April 2015	Ofatumumab 100mg and 1,000mg concentrate for solution for infusion (Arzerra®)	Ofatumumab in combination with chlorambucil or bendamustine is indicated for the treatment of patients with chronic lymphocytic leukaemia who have not received prior therapy and who are not eligible for fludarabine-based therapy. **SMC restriction:** for use in patients who would not be considered for bendamustine therapy and who would receive chlorambucil-based therapy.	**Include** Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1047/15	Olaparib, 50mg, hard	Monotherapy for the maintenance treatment of adult patients	Not routinely available as local	16th November

resubmission 7th October 2016	capsules (Lynparza®)	with platinum-sensitive relapsed *BRCA*-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.	implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th January 2017 7th November 2016	2016
			Available from a specialist centre in another NHS board 5th December 2016	19th December 2016
1273/17 6th October 2017	Olaratumab 10mg/mL concentrate for solution for infusion (Lartruvo®)	In combination with doxorubicin for the treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin. **SMC restriction:** for use in combination with doxorubicin as first-line treatment for advanced soft-tissue sarcoma not amenable to curative treatment with surgery or radiotherapy	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th December 2017 1st November 2017	22nd November 2017
823/12 9th November 2012	Olmesartan medoxomil / amlodipine besilate / 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	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary (Joint Formulary) 5th December 2012	17th December 2012
974/14 resub 5th December 2014	Olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®)	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.	**Exclude** Pending protocol (Joint Formulary) 4th March 2015	16th March 2015
1017/14 5th December 2014	Omalizumab 150mg solution for injection (Xolair®)	As add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment. **SMC restriction:** use in adults and adolescents with chronic spontaneous urticaria who have an inadequate response to combination therapy with H1 antihistamines, leukotriene receptor antagonists (LTRA) and H2 antihistamines, used according to current treatment guidelines.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 4th March 2015	16th March 2015
1051/15	Ombitasvir 12.5mg/	• Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in	**Include**	15th June 2015

8th May 2015	paritaprevir 75mg/ ritonavir 50mg (Viekirax®) film-coated tablet and dasabuvir 250mg (Exviera®) film-coated tablet.	combination with dasabuvir (Exviera®) with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults • Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with ribavirin for the treatment of genotype 4 CHC in adults	Pending protocol Case by case form requires to be completed before treatment initiation 1st June 2015	
			Routinely available in line with national guidance (NHS Scotland Hepatitis C January 2017 guidelines) 6th March 2017	15th March 2017
912/13 4th October 2013	Ondansetron 4mg, 8mg orodispersible films (Setofilm®)	**In adults:** • Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy. • Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy. • Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV). **In paediatric populations:** • Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥4 years. **SMC restriction:** ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing.	**Include** Specialist initiation as per SMC restrictions 4th December 2013	18th December 2013
1127/16 5th February 2016	Oseltamivir 30mg, 45mg, 75mg capsules and 6mg/mL powder for oral suspension (Tamiflu®)	Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms	**Include** 2nd March 2016	16th March 2016
1214/17 13th January 2017	Osimertinib 40mg and 80mg film-coated tablets (Tagrisso®)	Treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC). **SMC Restriction:** in patients who have received previous treatment with an EGFR tyrosine kinase inhibitor.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 6th February 2017	15th February 2017
			Routinely available in line with local	15th March

			guidance 6th March 2017	2017
968/14 resub 9th January 2015	Paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®)	In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd March 2015	16th March 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
SMC 1276/17	Palbociclib 75mg, 100mg and 125mg hard capsules (Ibrance®)	Treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer: - in combination with an aromatase inhibitor; - in combination with fulvestrant in women who have received prior endocrine therapy. In pre- or peri-menopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **SMC restriction**: in combination with an aromatase inhibitor for first-line treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th February 2018 6th December 2017	21st December 2017
1181/16 5th August 2016	Paliperidone palmitate 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection (Trevicta®)	Paliperidone palmitate (Trevicta®), a three-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2nd November 2016 7th September 2016	20th September 2016
			Available in line with local guidance for prescribing 5th October 2016	18th October 2016
838/13 11th January 2013	Palonosetron 500microgram soft capsules (Aloxi®)	Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question	15th March 2013

			(Joint Formulary) 6th March 2013	
1073/15 10th July 2015	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.	**Include** Specialist consultant initiation 2nd September 2015	14th September 2015
1122/16 8th January 2016	Panobinostat 10mg, 15mg and 20mg hard capsules (Farydak®)	In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
1048/15 7th August 2015	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.	**Include** Specialist consultant initiation 7th September 2015	14th September 2015
1197/16 7th October 2016	Pegaspargase (Oncaspar®) 750U/mL solution for injection/infusion	As a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th January 2017 7th November 2016	16th November 2016
			Available in line with local guidance for prescribing 5th December 2016	19th December 2016
794/12 8th June 2012	Pegylated interferon alfa-2b 50, 80, 100, 120 or 150 micrograms powder for solution for injection in pre-filled pen (ViraferonPeg®)	In a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 4th July 2012	18th July 2012
871/13 10th May 2013	Pegylated interferon alpha-2a, 135 and 180 microgram/mL pre-filled syringe, 135 and 180 microgram/mL pre-filled pen	In combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA). When deciding to initiate treatment in childhood, it is important to	**Include** Specialist consultant initiation 15th July 2013	25th July 2013

	(Pegasys®)	consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case-by-case basis. **SMC restriction:** prescribing by specialist in paediatric infectious disease or paediatric gastroenterology		
1018/14 5th December 2014	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.	**Include** Consultant initiation 4th February 2015	16th February 2015
158/05 resubmission 6th October 2017	Pegvisomant 10mg, 15mg, 20mg, 25mg and 30mg powder and solvent for solution for injection (Somavert®)	Treatment of adult patients with acromegaly who have had an inadequate response to surgery and / or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise IGF-1 [insulin-like growth factor 1] concentrations or was not tolerated.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 10th January 2018 1st November 2017	22nd November 2017
1086/15 9th October 2015	Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd November 2015	16th November 2015
1204/17 9th December 2016	Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)	Treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) and who have received at least one prior chemotherapy regimen. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 11th January 2017	24th January 2017
			Routinely available in line with local guidance 6th February 2017	15th February 2017
1239/17 9th June 2017	Pembrolizumab 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion (Keytruda®)	As monotherapy for the first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) with a ≥50% tumour proportion score (TPS) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) positive tumour mutations. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with local guidance 10th August 2017	23rd August 2017

770/12 resub 7th November 2014	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 in patients whose disease has not progressed immediately following platinum-based chemotherapy.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd February 2015	16th February 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
819/12 9th November 2012	Perampanel, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film-coated tablets (Fycompa®)	Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. **SMC restriction:** use as a second-line adjunctive treatment in patients with refractory partial onset epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy	**Include** Specialist consultant initiation 9th January 2013	22nd January 2013
835/13 5th July 2013	Pirfenidone 267mg capsule (Esbriet®)	In adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). **SMC restriction:** For use in patient with a predicted forced vital capacity (FVC) less than or equal to 80%.	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated 9th September 2013	18th September 2013
			Include Consultant initiation as per guideline 3rd June 2015	15th June 2015
972/14 resub 7th November 2014	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 regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd February 2015	16th February 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1032/15 6th March 2015	Ponatinib 15mg, 45mg film-coated tablets (Iclusig®)	Adult patients with: • Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for	**Include** Consultant initiation, as per West of Scotland Cancer Network protocol	20th May 2015

		whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. • Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.	11th May 2015	
999/14 5th September 2014	Posaconazole 100mg gastro-resistant tablets (Noxafil®)	Treatment of the following fungal infections in adults: • Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; • Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; • Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; • Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. for prophylaxis of invasive fungal infections in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; • Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections. **SMC restriction:** to patients in whom there is a specific risk of *Aspergillus* infection or where fluconazole or itraconazole are not tolerated on the advice of local microbiologists or specialists in infectious diseases.	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated 5th November 2014	19th November 2014
			Routinely available in line with local guidance 8th May 2017	22nd May 2017
1067/15 5th June 2015	Posaconazole 300mg concentrate for solution for infusion (Noxafil®)	Use in the treatment of the following fungal infections in adults: • Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; • Fusariosis in patients with disease that is refractory* to	**Include** Specialist consultant recommendation (microbiology or infectious diseases) 27th August 2015	1st September 2015

		amphotericin B or in patients who are intolerant of amphotericin B; • Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; • Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.		
		For prophylaxis of invasive fungal infections (IFI) in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing IFI; Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high risk of developing IFI.	**Exclude** Pending protocol (Joint Formulary) 27th August 2015	1st September 2015
765/12 4th May 2012	Pregabalin oral solution (Lyrica®)	Treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalization and the treatment of Generalised Anxiety Disorder in adults. **SMC restriction:** pregabalin oral solution should be prescribed only for patients who find it difficult to or are unable to swallow tablets. **The following SMC restrictions to the use of pregabalin apply:** • Pregabalin is restricted to use in patients with peripheral neuropathic pain who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments for peripheral neuropathic pain. Treatment should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximally tolerated therapeutic dose. • Pregabalin is restricted to use as adjunctive therapy in adults with partial seizures with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug	**Include** Use in patients where pregabalin is required as per SMC restrictions but are unable to swallow the tablet formulation 6th June 2012	20th June 2012

		such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.		
1185/16 9th September 2016	Progesterone 100mg vaginal tablets (Lutigest®)	Luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th December 2016 5th October 2016	18th October 2016
			Available from a specialist centre in another NHS board 2nd November 2016	16th November 2016
1077/15 4th September 2015	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	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd November 2015	16th November 2015
902/13 9th August 2013	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. **SMC restriction**: to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors or protease inhibitors or when these options are compromised due to drug-drug interactions; raltegravir should to be prescribed under the supervision of specialists in paediatric HIV.	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
1102/15 9th October 2015	Raltegravir granules for oral suspension 100mg (Isentress®) SMC	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks. **SMC restriction:** patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir granules should be prescribed under the supervision of specialists in paediatric HIV.	**Include** Specialist consultant initiation 2nd December 2015	16th December 2015
1113/15 9th October 2015	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. **SMC restriction:** patients who are intolerant or resistant to non-	**Include** Specialist consultant initiation 2nd December 2015	16th December 2015

		nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir chewable tablets should be prescribed under the supervision of specialists in paediatric HIV.		
1280/17 6th October 2017	Raltegravir 600mg film-coated tablets (Isentress®)	In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults and paediatric patients weighing at least 40kg. **SMC restriction:** patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions.	Routinely available in line with local guidance 1st November 2017	22nd November 2017
711/11 (resub) 9th November 2012	Ranibizumab, 10mg/mL solution for injection (Lucentis®)	Treatment of visual impairment due to diabetic macular oedema (DMO) in adults. **SMC restriction:** treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.	**Include** Specialist consultant initiation Case by case form requires to be completed before treatment is initiated 3rd December 2012	17th December 2012
732/11 resub 5th April 2013	Ranibizumab, 10mg/mL solution for injection (Lucentis®)	Treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (RVO) (branch [BRVO] or central [CRVO]) in adults	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated in the interim 5th June 2013	17th June 2013
907/13 4th October 2013	Ranibizumab, 10mg/mL, solution for injection (Lucentis®)	Treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults	**Include** Pending protocol Case by case form must be completed before prescribing can be initiated 11th November 2013	18th November 2013
1031/15 6th March 2015	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.	**Include** Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1168/16 8th July 2016	Rilpivirine 25mg film-coated tablet (Edurant®)	In combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL) ≤ 100,000 HIV-1 RNA copies/mL.	Available from a specialist centre in another NHS board. 10th August 2016	15th August 2016
951/14	Rilpivirine 25mg,	Treatment of adults infected with human immunodeficiency virus	**Include**	19th May 2014

7th March 2014	emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®)	type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load ≤100,000 HIV-1 RNA copies/mL. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®.	Consultant initiation, as per local HIV guidelines 7th May 2014	
893/13 9th August 2013	Rifaximin 550mg film-coated tablets (Targaxan®)	Reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥18 years of age	**Include** Specialist initiation 7th October 2013	16th October 2013
1189/16 9th September 2016	Rilpivirine/ emtricitabine/ tenofovir alafenamide 200mg/25mg/25mg film-coated tablets (Odefsey®)	Treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg), infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV-1 RNA ≤100,000 copies/mL.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th December 2016 5th October 2016	18th October 2016
			Available in line with local guidance for prescribing 7th November 2016	16th November 2016
1001/14 7th November 2014	Riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®)	Chronic thromboembolic pulmonary hypertension (CTEPH): Treatment of adult patients with World Health Organisation (WHO) functional class II to III with • inoperable CTEPH, • persistent or recurrent CTEPH after surgical treatment, to improve exercise capacity. **SMC restriction:** for patients in whom a PDE5 inhibitor is inappropriate, not tolerated, or ineffective. It is restricted to prescribing by specialists in the Scottish Pulmonary Vascular Unit.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd February 2015	16th February 2015
1056/15 5th June 2015	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. Efficacy has been shown in a PAH population including aetiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease. **SMC restriction:** for use as a PAH-specific monotherapy as an alternative treatment option to endothelin receptor antagonist (ERA) monotherapy in adult patients with PAH of WHO FC II to III. It is restricted to	**Include** Specialist initiation 7th September 2015	14th September 2015

		initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or by similar specialists.		
894/13 9th August 2013	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) and microscopic polyangiitis. **SMC restriction:** to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide.	**Include** Pending protocol 7th October 2013	16th October 2013
975/14 6th June 2014	Rituximab 1400mg solution for subcutaneous injection (Mabthera®)	Non-Hodgkin's lymphoma (NHL) in adults: - previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy; - maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy; - treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy. **SMC restriction:** Subcutaneous rituximab is accepted for use in line with previous SMC advice for intravenous rituximab i.e. accepted within licensed indication as above except in the maintenance setting, where use is restricted to patients who have responded to induction therapy with rituximab plus chemotherapy.	**Include** Consultant initiation as per West of Scotland Cancer Network protocols 13th August 2014	22nd August 2014
852/13 8th February 2013	Rivaroxaban 15mg and 20mg film-coated tablets (Xarelto®)	Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis and PE in adults	**Exclude** Pending protocol (Joint Formulary) Case by case form requires to be completed before treatment is initiated in the interim 29th April 2013	13th May 2013
			Routinely available in line with local guidance 11th January 2017	24th January 2017
1266/17 11th September 2017	Rolapitant (as hydrochloride monohydrate) 90mg film-coated tablets (Varuby®)	Prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Rolapitant is given as part of combination therapy. **SMC restriction:** as a first-line option in adults undergoing highly emetogenic chemotherapy (HEC).	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th December 2017	20th September 2017

			6th September 2017	
			Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Joint Formulary) 6th December 2017	21st December 2017
795/12 8th June 2012	Rufinamide 40mg/mL oral suspension (Inovelon®)	Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older. **SMC restriction:** restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.	**Include** Specialist consultant initiation at Yorkhill Hospital, as per SMC restrictions 8th August 2012	15th August 2012
867/13 resub 6th February 2015	Ruxolitinib (as phosphate) 5mg, 15mg, & 20mg tablets (Jakavi®)	Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 2nd March 2015	16th March 2015
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
1132/16 5th February 2016	Sacubitril/ valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets (Entresto®)	In adults for treatment of symptomatic chronic heart failure with reduced ejection fraction	Available in line with local guidance for prescribing 28th April 2016	12th May 2016
918/13 8th November 2013	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 triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. **SMC restriction:** as an alternative dipeptidyl peptidase-4 inhibitor option.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary) 4th December 2013	18th December 2013
870/13 10th May 2013	Saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg tablets (Komboglyze®)	Adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in	17th June 2013

		combination of saxagliptin and metformin as separate tablets. **SMC restriction:** use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate.	question (Joint Formulary) 5th June 2013	
772/12 resub 10th October 2014	Saxagliptin, 2.5mg and 5mg, film-coated tablets (Onglyza®)	Adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary) 5th November 2014	19th November 2014
929/13 6th December 2013	Saxagliptin plus metformin, 2.5mg / 850mg and 2.5mg / 1000mg filmcoated tablets (Komboglyze®)	In combination with a sulphonylurea (i.e. 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 when the maximally tolerated dose of both metformin and the sulphonylurea does not provide adequate glycaemic control.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary) 8th January 2014	22nd January 2014
1255/17 9th June 2017	Saxagliptin 5mg / dapagliflozin 10mg film-coated tablets (Qtern®)	In adults aged 18 years and older with type 2 diabetes mellitus: • to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Qtern® do not provide adequate glycaemic control, • when already being treated with the free combination of dapagliflozin and saxagliptin **SMC restriction:** for use in combination with metformin when the use of a sulphonylurea is inappropriate	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (local guidance) 9th August 2017	23rd August 2017
1054/15 8th May 2015	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. **SMC restriction:** for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 1st June 2015	15th June 2015
1159/16 10th June 2016	Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®)	Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy.	Available in line with local guidance for prescribing 10th August 2016	15th August 2016
1167/16	Secukinumab 150mg solution for injection in pre-	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to	Not routinely available as local implementation plans are being	15th August 2016

8th July 2016	filled pen and pre-filled syringe (Cosentyx®)	previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **SMC restriction:** Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination	developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th October 2016 10th August 2016	
			Available in line with local guidance for prescribing 10th October 2016	18th October 2016
809/12 9th November 2012	Sildenafil (as citrate) 20mg film-coated tablets and 10mg/mL powder for oral solution (Revatio®)	Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease. **SMC restriction:** restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service.	**Include** Specialist consultant initiation 5th December 2012	17th December 2012
988/14 5th September 2014	Simeprevir 150mg hard capsules (Olysio ®)	In combination with other medicinal products for the treatment of chronic hepatitis C in adult patients.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 20th October 2014	24th October 2014
			Routinely available in line with national guidance (NHS Scotland Hepatitis C January 2017 guidelines) 6th March 2017	15th March 2017
1083/15 7th August 2015	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.	**Include** 2nd September 2015	14th September 2015
914/13 4th October 2013	Sodium phenylbutyrate granules 483mg/g (Pheburane®)	Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.	**Include** Specialist consultant initiation 4th December 2013	18th December 2013
964/14 9th May 2014	Sofosbuvir 400mg tablet (Sovaldi®)	In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. **SMC restriction:** Sofosbuvir is accepted for use in patients with genotypes 1 to 6. Use in treatment-naive patients with genotype 2 is restricted to	**Include** Pending protocol Case by case form requires to be completed before treatment initiation	17th June 2014

		those who are ineligible for, or are unable to tolerate, peginterferon alfa. Use of the 24-week interferon-free regimen of sofosbuvir in combination with ribavirin in patients with genotype 3 is restricted to those who are ineligible for, or are unable to tolerate, peginterferon alfa.	9th June 2014	
			Routinely available in line with national guidance (NHS Scotland Hepatitis C January 2017 guidelines) 6th March 2017	15th March 2017
SMC 1195/16 7th October 2016	Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®)	Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** in patients with genotype 3 (GT3) chronic HCV infection.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 9th January 2017 7th November 2016	16th November 2016
			Available in line with local guidance for prescribing 5th December 2016	19th December 2016
1271/17 9th October 2017	Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®)	Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction**: in patients with • genotype 2, 5 or 6 chronic HCV infection • decompensated cirrhosis, irrespective of chronic HCV genotype	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th December 2017 4th October 2017	13th October 2017
			Routinely available in line with national guidance NHS Scotland Hepatitis C guidance 10th January 2018	24th January 2018
945/14 7th February 2014	Solifenacin succinate plus tamsulosin hydrochloride 6mg / 0.4mg modified release tablet (Vesomni®)	Treatment of moderate to severe 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.	**Include** 12th March 2014	24th March 2014
1055/15 5th June 2015	Sorafenib 200mg film-coated tablets (Nexavar®)	Treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.	**Include** Specialist initiation 7th September 2015	14th September 2015
482/08 resub 4th December 2015	Sorafenib 200mg film-coated tablets (Nexavar®)	Treatment of hepatocellular carcinoma. **SMC restriction:** in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016

			Available from a specialist centre in another NHS board 7th November 2016	16th November 2016
524/08 resubmission 11th September 2017	Stiripentol 250mg and 500mg hard capsule, 250mg and 500mg powder for oral suspension in sachet (Diacomit®)	In conjunction with clobazam and valproate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI; Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 1st November 2017 6th September 2017	20th September 2017
			Routinely available in line with local guidance 1st November 2017	22nd November 2017
1035/15 6th March 2015	Sucroferric oxyhydroxide 500mg chewable tablets (Velphoro®)	Control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD). It should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy vitamin D3 or one of its analogues, or calcimimetics to control the development of renal bone disease.	**Include** Specialist initiation 6th May 2015	20th May 2015
527/09 resub 8th February 2013	Sugammadex 100mg/mL (1mL, 2mL, 5mL) solution for injection (Bridion®)	Reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents. This resubmission is for the part of the indication relating to routine reversal of neuromuscular blockade. **SMC restriction:** only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/chest surgery) or where prompt reversal of neuromuscular block is required	**Include** Specialist use as per SMC restrictions 3rd April 2013	17th April 2013
1041/15 6th March 2015	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.	**Include** Consultant initiation 6th May 2015	20th May 2015
710/11 (resub) 8th June 2012	Tadalafil 20mg tablets (Adcirca®)	Treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II and III, to improve exercise capacity. **SMC restriction:** To initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists.	**Include** Initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists 8th August 2012	15th August 2012
1085/15	Tafluprost 15micrograms/mL	Reduction of intraocular pressure in adult patients with open	**Include**	20th October

7th August 2015	and timolol 5mg/mL preservative-free eye drops (Taptiqom®)	angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative-free eye drops. **SMC restriction:** to use in patients who have proven sensitivity to preservatives.	Specialist initiation 7th October 2015	2015
1080/15 10th July 2015	Tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®)	The treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. **SMC restriction:** • Use in patients with ABSSSI caused by Gram-positive Staphylococcus aureus (specifically methicillin-resistant Staphylococcus aureus [MRSA] isolates) • Use of tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacteria	**Include** Specialist consultant recommendation (microbiology or infectious diseases 2nd September 2015	14th September 2015
802/12 10th August 2012	Tegafur/gimeracil/oteracil 15mg/4.35mg/11.8mg and 20mg/5.8mg/15.8mg hard capsules (Teysuno®)	Tegafur/gimeracil/oteracil is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin **SMC restriction:** tegafur/gimeracil/oteracil is restricted to use in patients with advanced gastric cancer who are unsuitable for an anthracycline, fluorouracil and platinum triplet first line regimen	**Exclude** Pending protocol (Joint Formulary) 3rd October 2012	11th October 2012
			Include Specialist consultant initiation as per West of Scotland cancer Network protocol 5th June 2013	17th June 2013
904/13 9th August 2013	Tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Viread®)	*HIV-1 infection* - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. *Hepatitis B infection* - for the treatment of chronic hepatitis B in adolescents aged 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric infectious diseases.	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
905/13 9th August 2013	Tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®)	*HIV-1 infection* - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a	**Include** Specialist consultant initiation 6th November 2013	18th November 2013

		solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate. *Hepatitis B infection* - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. **SMC restriction:** in patients <18 years, to be prescribed under the supervision of specialists in paediatric infectious diseases.		
900/13 9th August 2013	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, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents **SMC restriction:** to be prescribed under the supervision of specialists in paediatric infectious diseases.	**Include** Specialist consultant initiation 6th November 2013	18th November 2013
940/14 7th February 2014	Teriflunomide, 14mg, film-coated tablets (Aubagio®)	Treatment of adults with relapsing remitting multiple sclerosis (MS). **SMC restriction:** as an alternative to treatment with interferon beta or glatiramer acetate. Teriflunomide is not expected to be used for the treatment of patients with highly active disease.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 7th April 2014	10th April 2014
941/14 10th January 2014	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. **SMC restriction:** to use in patients who have proven sensitivity to preservatives.	**Include** Specialist initiation 12th March 2014	24th March 2014
1061/15 5th June 2015	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.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in	1st September 2015

			the formulary (Joint Formulary) 27th August 2015	
1028/15 10th July 2015	Tiotropium, 2.5 microgram, solution for inhalation (Spiriva® Respimat®)	As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta2 agonists and who experienced one or more severe exacerbations in the previous year.	**Include** Pending protocol 2nd September 2015	14th September 2015
			Routinely available in line with local guidance 8th May 2017	22nd May 2017
SMC 411/07 resubmission	Tiotropium 2.5 microgram inhalation solution (Spiriva Respimat®)	As a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD)	Routinely available in line with national guidance 6th December 2017	21st December 2017
1099/15 9th October 2015	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).	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary 2nd December 2015	16th December 2015
			Routinely available in line with local guidance 8th May 2017	22nd May 2017
783/12 4th May 2012	Tobramycin 28mg inhalation powder, hard capsules (TOBI Podhaler®)	Suppressive therapy of chronic pulmonary infection due to *Pseudomonas aeruginosa* in adults and children aged 6 years and older with cystic fibrosis	**Exclude** Clinicians have not responded to an invitation to apply for formulary inclusion for this medicine (Joint Formulary) 4th July 2012	18th July 2012
774/12 resub 10th August 2012	Tocilizumab, 20mg/mL, concentrate for solution for infusion (RoActemra®)	Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying antirheumatic drugs or tumour necrosis factor (TNF) antagonists. **SMC restriction:** tocilizumab is restricted for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005)	**Include** Specialist consultant initiation Case by case form must be completed before prescribing can be initiated 3rd October 2012	11th October 2012
			Include Consultant initiation, as per approved guideline	14th April 2015

			1st April 2015	
930/13 6th December 2013	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, who have responded inadequately to previous therapy with methotrexate. Tocilizumab can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate.	**Include** Consultant initiation Case by case form must be completed before prescribing can be initiated 5th February 2014	10th February 2014
982/14 4th July 2014	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 who have either responded inadequately to, or who were intolerant to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. Tocilizumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate. **SMC restriction**: tocilizumab is restricted to use in accordance with current eligibility and continuation rules for biologic therapies in rheumatoid arthritis.	**Include** Consultant initiation Case by case form requires to be completed before treatment initiation 13th August 2014	22nd August 2014
			Include Consultant initiation, as per approved guideline 1st April 2015	14th April 2015
1114/15 4th December 2015	Tolvaptan 15mg, 30mg, 45mg, 60mg and 90mg tablets (Jinarc®)	To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
1161/16 5th August 2016	Trametinib 0.5mg and 2mg film-coated tablets (Mekinist®)	In combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. **SMC restriction:** to first-line treatment.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th November 2016 7th September 2016	20th September 2016
			Available from a specialist centre in another NHS board 10th October 2016	18th October 2016
928/13 6th December	Trastuzumab, 600mg/5mL solution for injection	Treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of	**Include** Pending protocol	10th February 2014

2013	(Herceptin®)	settings (full details of licensed indication presented later in advice document). Trastuzumab should only be used in patients with metastatic or early breast cancer whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. **SMC restriction:** Subcutaneous trastuzumab injection is accepted for use in line with previous SMC advice for intravenous trastuzumab (this excludes its use in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab).	Case by case form requires to be completed before treatment initiation 5th February 2014	
			Include Consultant initiation, as per West of Scotland Cancer Network protocol 11th May 2015	20th May 2015
623/10 resub 4th September 2015	Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin®)	In combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Trastuzumab should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay	**Include** Pending protocol Case by case requires to be completed before treatment initiation 2nd November 2015	16th November 2015
			Available in line with local guidance for prescribing 29th August 2016	20th September 2016
990/14 resubmission 10th March 2017	Trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla®)	As a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 5th June 2017 5th April 2017	19th April 2017
			Routinely available in line with local guidance 8th May 2017	22nd May 2017
1091/15 4th September 2015	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	**Include** Specialist initiation 2nd December 2015	16th December 2015
1103/15 9th October 2015	Triamcinolone hexacetonide 20mg/mL suspension for injection	Juvenile idiopathic arthritis (JIA).	**Include** Specialist initiation 4th November 2015	16th November 2015
1221/17	Trifluridine/ tipiracil (as hydrochloride), 15mg/6.14mg	Treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not	Not routinely available as local implementation plans are being	15th February

13th January 2017	and 20mg/8.19mg film-coated tablets (Lonsurf®)	considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents, and anti-epidermal growth factor receptor agents.	developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 6th March 2017 6th February 2017	2017
			Routinely available in line with local guidance 6th March 2017	15th March 2017
834/13 11th January 2013	Ulipristal acetate, 5mg, tablet (Esmya®)	Pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months.	**Include** Specialist consultant initiation 6th March 2013	15th March 2013
1128/16 8th January 2016	Ulipristal acetate, 5mg, tablet (Esmya®)	Intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 8th February 2016	11th February 2016
1004/14 7th November 2014	Umeclidinium, 55 micrograms, powder for inhalation (Incruse®)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	**Exclude** Pending protocol (Joint Formulary) 4th February 2015	16th February 2015
			Include 1st Choice within therapeutic class 27th August 2015	1st September 2015
978/14 resub 9th January 2015	Umeclidinium / vilanterol, 55/22 micrograms, inhalation powder (Anoro®)	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	**Exclude** Pending protocol (Joint Formulary) 4th March 2015	16th March 2015
			Include 1st Choice within therapeutic class 27th August 2015	1st September 2015
889/13 5th July 2013	Ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®)	Dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s). Treatment of primary biliary cirrhosis provided there is no	**Include** Specialist initiation 14th August 2013	26th August 2013

		decompensated hepatic cirrhosis		
944/14 7th February 2014	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. **SMC restriction**: for use in patients with active psoriatic arthritis who have failed on, or are unsuitable for, treatment with an anti-TNF drug.	**Include** Consultant initiation Case by case form requires to be completed before treatment initiation 12th March 2014	24th March 2014
			Include Consultant initiation as per approved guideline 8th February 2016	11th February 2016
1115/15 4th December 2015	Ustekinumab 45mg solution for injection and prefilled syringe (Stelara®)	Treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. **SMC restriction:** continued treatment should be restricted to patients who achieve at least 75% improvement in their Psoriasis Area and Severity Index (PASI 75) within 16 weeks.	**Include** Consultant initiation as per approved guideline 3rd February 2016	11th February 2016
1250/17 9th June 2017	Ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (Stelara®)	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 or have medical contraindications to such therapies.	Routinely available in line with local guidance 10th August 2017	23rd August 2017
1045/15 10th April 2015	Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®)	Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 11th May 2015	20th May 2015
1064/15 5th June 2015	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. **SMC restriction:** for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNFα antagonist.	**Include** Pending protocol Case by case requires to be completed before treatment initiation 7th September 2015	14th September 2015
681/11 resub 7th September	Velaglucerase alfa 400 units powder for solution for infusion (VPRIV®)	Long-term enzyme replacement therapy in patients with type 1 Gaucher disease	**Include** Specialist consultant initiation	19th November 2012

2012			Case by case form must be completed before prescribing can be initiated 5th November 2012	
792/12 resub 8th November 2013	Vemurafenib 240mg film-coated tablet (Zelboraf®)	As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. **SMC restriction:** for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma	**Include** Pending protocol Case by case form requires to be completed before treatment initiation 13th January 2014	22nd January 2014
1249/17 7th July 2017	Venetoclax, 10mg, 50mg and 100mg film-coated tablets (Venclyxto®)	As monotherapy for the treatment of chronic lymphocytic leukaemia (CLL): • in the presence of 17p deletion or *TP53* mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor. • in the absence of 17p deletion or *TP53* mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 4th October 2017 22nd August 2017	23rd August 2017
			Routinely available in line with local guidance 13th September 2017	20th September 2017
826/12 7th December 2012	Vildagliptin 50mg tablets (Galvus®)	Treatment of type 2 diabetes mellitus in adults as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. **SMC restriction:** for use in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.	**Exclude** Clinicians do not support the formulary inclusion (Joint Formulary) 6th February 2013	20th February 2013
875/13 resub 8th November 2013	Vildagliptin 50mg tablets (Galvus®)	Treatment of type 2 diabetes mellitus in adults as 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. **SMC restriction:** as an alternative dipeptidyl peptidase-4 inhibitor option.	**Exclude** Medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question (Joint Formulary) 4th December 2013	18th December 2013
1158/16 10th June 2016	Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®)	Treatment of major depressive episodes in adults. **SMC restriction:** patients who have experienced an inadequate response (either due to lack of adequate efficacy and/or safety concerns/intolerability) to two or more previous antidepressants.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 7th September 2016 10th August 2016	15th August 2016

			Available in line with local guidance for prescribing 7th September 2016	20th September 2016
949/14 7th February 2014	Zonisamide 25mg, 50mg and 100mg capsules (Zonegran®)	As adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above. **SMC restriction:** on advice from specialists (paediatric neurologists or paediatricians with an expertise in epilepsy).	**Include** Specialist Consultant initiation 7th May 2014	19th May 2014