

# NHS Grampian Formulary Group Decisions for SMC advice published April 2012 to March 2015



This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) advice published April 2012 to March 2015.

For the latest Formulary Group decisions see the [Grampian Medicines Management website](#).

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Updated to November 2021 Formulary Group decisions.

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# NHS Grampian Formulary Group decisions for SMC accepted medicines published April 2012 to March 2013



This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) accepted medicines published April 2012 to March 2013.

For the latest Formulary Group decisions see the [Grampian Medicines Management website](#).

**November 2021**

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NHS Grampian Formulary Group Decisions for SMC advice published April 2012 to March 2013

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®)	<a href="#">811/12</a>	For the treatment of actinic keratosis of mild to moderate intensity on the face and scalp.	Routinely available in line with local guidance Updates decision 15/01/13	21/01/2020
abiraterone acetate 250mg tablets (Zytiga®)	<a href="#">764/12</a>	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. <b>SMC restriction:</b> abiraterone is restricted to use in patients who have received only one prior chemotherapy regimen.	Included on the Grampian Joint Formulary for the indication in question; restricted use, The 250mg tablet was discontinued 31 August 2017, replaced by a 500mg strength tablet.	21/08/2012
acclidinium 322micrograms inhalation powder (Eklira Genuair®)	<a href="#">810/12</a>	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Included on the Grampian Joint Formulary for the indication in question Updates decision 18/12/12	19/02/2013
adalimumab 40mg solution for injection in pre-filled pen, pre-filled syringe and vial (Humira®)	800/12	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA329 Updates decision 17/07/12	17/03/2015
adalimumab 40mg solution for injection in pre-filled pen, pre-filled syringe and vial (Humira®)	<a href="#">824/12</a>	Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.	Not recommended for use within NHS Scotland	20/11/2012

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alteplase 10mg, 20mg, 50mg powder and solvent for solution for injection and infusion (Actilyse®)	<a href="#">714/11</a>	For the fibrinolytic treatment of acute ischaemic stroke, commenced within 3 to 4.5 hours of stroke symptom onset and after prior exclusion of intracranial haemorrhage by means of appropriate imaging techniques (extension licence of 3 hour time limit).	Included on the Grampian Joint Formulary for the indication in question; restricted use	19/06/2012
amifampridine 10mg tablets as phosphate (Firdapse®)	<a href="#">660/10</a>	For the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adults.	Not recommended for use within NHS Scotland	21/08/2012
apixaban 2.5mg, 5mg film-coated tablets (Eliquis®)	<a href="#">836/13</a>	For the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II).	Included on the Grampian Joint Formulary for the indication in question Updates decision 19/03/13	19/11/2013
azilsartan medoxomil 20mg, 40mg, 80mg tablets (Edarbi®)	<a href="#">803/12</a>	Treatment of essential hypertension in adults.	Not recommended for use within NHS Scotland	17/07/2012
azithromycin dihydrate 15mg/g eye drops (Azyter®)	<a href="#">804/12</a>	Local antibacterial treatment of conjunctivitis caused by susceptible strains: - Purulent bacterial conjunctivitis - Trachomatous conjunctivitis caused by Chlamydia trachomatis.	Not recommended for use within NHS Scotland	17/07/2012
belatacept 250mg powder for concentrate for solution for infusion (Nulojix®)	<a href="#">786/12</a>	In combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin (IL)-2 receptor antagonist for induction therapy to this belatacept-based regimen.	Not recommended for use within NHS Scotland	19/06/2012

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bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®)	<a href="#">778/12</a>	Bevacizumab in combination with capecitabine is indicated for first-line treatment of patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate.	Not recommended for use within NHS Scotland	15/05/2012
bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®)	<a href="#">853/13</a>	Bevacizumab, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.	Not recommended for use within NHS Scotland	19/03/2013
bimatoprost 0.3mg/mL single-dose eye drops (Lumigan UD®)	<a href="#">839/13</a>	Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers). <b>SMC restriction:</b> to use in patients who have proven sensitivity to the preservative benzalkonium chloride.	Included on the Grampian Joint Formulary for the indication in question; restricted use	16/04/2013
bortezomib 3.5mg powder for subcutaneous injection (Velcade®)	<a href="#">822/12</a>	In combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant. 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	15/01/2013

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budesonide 3mg gastro-resistant capsule (Budenofalk®)	<a href="#">828/12</a>	Symptomatic relief of chronic diarrhoea due to collagenous colitis	Included on the Grampian Joint Formulary for the indication in question; restricted use Updates decision 19/02/13	19/03/2013
budesonide 9mg gastro-resistant granules (Budenofalk®)	<a href="#">831/12</a>	Induction of remission in patients with active collagenous colitis	Included on the Grampian Joint Formulary for the indication in question; restricted use Updates decision 19/02/13	19/03/2013
catumaxomab 10microgram, 50microgram concentrate for solution for infusion (Removab®)	<a href="#">788/12</a>	Intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible.	Not recommended for use within NHS Scotland	17/04/2012
ceftaroline fosamil 600mg powder for concentrate for solution for infusion (Zinforo®)	<a href="#">830/12</a>	Treatment of complicated skin and soft tissue infections in adults. <b>SMC restriction:</b> 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 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.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	19/02/2013

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clostridium botulinum type A toxin-haemagglutinin complex 300units, 500units (Dysport®)	<a href="#">353/07</a>	For focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy. <b>SMC restriction:</b> for focal spasticity of the upper limbs associated with stroke.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	19/02/2013
coleciferol 800 international units (equivalent to 20micrograms vitamin D3) capsules (Fultium-D3®)	<a href="#">801/12</a>	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.	Included on the Grampian Joint Formulary for the indication in question	16/10/2012
coleciferol 800 international units (equivalent to 20micrograms vitamin D3) tablets (Desunin 800 IU®)	<a href="#">840/13</a>	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	Included on the Grampian Joint Formulary for the indication in question	19/03/2013
collagenase clostridium histolyticum 0.9mg powder and solvent for solution for injection (Xiapex®)	715/11	For the treatment of Dupuytren's contracture. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, ADVICE ARCHIVED - This medicine is now withdrawn from use/discontinued. Updates decision 18/09/12	15/08/2017

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dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®)	<a href="#">799/12</a>	Adults aged 18 and older with type 2 diabetes mellitus to improve glycaemic control as monotherapy/add-on combination therapy. <b>SMC restriction:</b> 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.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question, Updates decision 19/02/13	15/07/2014
decitabine 50mg powder for concentrate for solution for infusion (Dacogen®)	<a href="#">846/12</a>	Treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.	Not recommended for use within NHS Scotland	15/01/2013
dexamethasone 700microgram intravitreal implant (Ozurdex®)	<a href="#">652/10</a>	For the treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/12/2012
dexmedetomidine 100micrograms/mL concentrate for solution for infusion (Dexdor®)	<a href="#">784/12</a>	For sedation of 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).	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/07/2012



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eplerenone 25mg, 50mg film coated tablets (Inspra®)	<a href="#">793/12</a>	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%)	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	18/09/2012
etanercept 10mg, 25mg powder and solvent for solution for injection for paediatric use, 25mg, 50mg solution for injection in pre-filled syringe, 50mg solution for injection in pre-filled pen (Enbrel®)	842/13	For the treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents. <b>SMC restriction:</b> use within specialist rheumatology services (including those working within the network for paediatric rheumatology).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA373 Updates decision 19/03/13	19/01/2016
etanercept 10mg, 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®)	781/12	For the 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. <b>SMC restriction:</b> - 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA455 Updates decision 18/09/12	18/07/2017

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etanercept 10mg, 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®)	782/12	For the 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. <b>SMC restriction:</b> use within specialist rheumatology services (including those working within the network for paediatric rheumatology).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA373 Updates decision 19/06/12	19/01/2016
etoricoxib 30mg, 60mg, 90mg, 120mg film-coated tablets (Arcoxia®)	<a href="#">847/12</a>	Short-term treatment of moderate pain associated with dental surgery.	Not recommended for use within NHS Scotland	15/01/2013
everolimus 2.5mg, 5mg tablets (Votubia®)	<a href="#">787/12</a>	Treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.	Not recommended for use within NHS Scotland	17/04/2012
everolimus 5mg, 10mg tablets (Afinitor®)	777/12	Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA455 Updates decision 18/09/12	18/07/2017
exenatide 5micrograms, 10micrograms solution for injection pre-filled pen (Byetta®)	<a href="#">785/12</a>	Adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults who have not achieved adequate glycaemic control with these agents.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/07/2012

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fidaxomicin 200mg film-coated tablets (Dificlir®)	<a href="#">791/12</a>	Treatment of clostridium difficile infections (CDI) also known as C. Difficile-associated diarrhoea (CDAD). <b>SMC restriction:</b> Treatment of adults with a first CDI recurrence on the advice of local microbiologists or specialists in infectious diseases.	Included on the Grampian Joint Formulary for the indication in question; restricted use. Included pending protocol: inclusion in the NHS Grampian Staff Guidance For Optimising Use Of Alert (Restricted) Antimicrobials In Adults.	21/08/2012
fingolimod (as hydrochloride) 0.5mg hard capsules (Gilenya®)	<a href="#">763/12</a>	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 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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	16/10/2012

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Flutiform® 50microgram/5microgram, 125microgram/5microgram, 250microgram/10microgram metered dose inhaler (fluticasone propionate/formoterol fumarate)	<a href="#">736/11</a>	For the 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 - patients already adequately controlled on both an ICS and a LABA.	Included on the Grampian Joint Formulary for the indication in question Updates decision 18/12/12	15/01/2013
glycopyrronium 44micrograms hard capsules of inhalation powder (Seebri Breezhaler®)	<a href="#">829/12</a>	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question Updates decision 19/02/13	20/10/2015
golimumab 50mg solution for injection in pre-filled pen, pre-filled syringe (Simponi®)	<a href="#">674/11</a>	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. <b>SMC restriction:</b> 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.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	18/09/2012

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imatinib 100mg, 400mg film-coated tablets (Glivec®)	<a href="#">584/09</a>	Adjuvant treatment of adult patients who are at significant risk of relapse following resection of a KIT (CD117) positive gastrointestinal stromal tumour (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. <b>SMC restriction:</b> Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria).	Included on the Grampian Joint Formulary for the indication in question; restricted use	15/05/2012
infliximab 100mg powder for concentrate for solution for infusion (Remicade®)	854/13	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. <b>SMC restriction:</b> as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA329 Updates decision 16/04/13	17/03/2015
ingenol mebutate 150micrograms/g and 500micrograms/g gel (Picato®)	851/13	Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.	This medicine is now withdrawn from use/discontinued Updates decision 16/04/13	21/01/2020
insulin detemir 100units/mL solution for injection in cartridge, pre-filled pen (Levemir®)	<a href="#">780/12</a>	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. <b>SMC restriction:</b> in patients unable to achieve good glycaemic control with established insulins.	Included on the Grampian Joint Formulary for the indication in question	15/05/2012

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interferon beta-1a (Rebif®)	<a href="#">825/12</a>	Patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.	Not recommended for use within NHS Scotland	20/11/2012
ivabradine 5mg, 7.5mg film-coated tablets (Procoralan®)	<a href="#">805/12</a>	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. <b>SMC restriction:</b> for initiation only in patients whose resting heart rate remains ≥75 beats per minute despite optimal standard therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use Updates decision 18/12/12	15/01/2013
Jentadueto® 2.5mg/850mg, 2.5mg/1000mg film-coated tablets (linagliptin/metformin)	<a href="#">841/13</a>	For the treatment of adult patients with type 2 diabetes mellitus. <b>SMC restriction:</b> 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.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	19/02/2013
lanthanum carbonate 750mg, 1000mg oral powder (Fosrenol®)	<a href="#">821/12</a>	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). <b>SMC restriction:</b> 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.	Routinely available in line with local guidance Updates decision 15/01/13	20/02/2018

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mercaptopurine 20mg/mL oral suspension (Xaluprine®)	<a href="#">798/12</a>	For the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children.	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/09/2012
nepafenac 1mg/mL eye drops suspension (Nevanac®)	<a href="#">813/12</a>	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	18/12/2012
palonosetron 500microgram soft capsules (Aloxi®)	<a href="#">838/13</a>	Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question Updates decision 19/03/13	21/06/2016
pasireotide diaspertate 0.3mg, 0.6mg, 0.9mg solution for injection (Signifor®)	<a href="#">815/12</a>	Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.	Not recommended for use within NHS Scotland	16/10/2012
pazopanib 200mg, 400mg film-coated tablets (Votrient®)	<a href="#">820/12</a>	For the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. Efficacy and safety has only been established in certain STS histological tumour subtypes.	Not recommended for use within NHS Scotland	18/12/2012
pegylated interferon alfa-2b powder for solution for injection in pre-filled syringe (Viraferon Peg®)	794/12	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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA300 Updates decision 18/09/12	18/02/2014

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perampanel 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film-coated tablets (Fycompa®)	<a href="#">819/12</a>	<p>Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.</p> <p><b>SMC restriction:</b> 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.</p>	Included on the Grampian Joint Formulary for the indication in question; restricted use	15/01/2013
pregabalin 20mg/mL oral solution (Lyrica®)	<a href="#">765/12</a>	<p>For the 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 (GAD) in adults.</p> <p><b>SMC restriction:</b> pregabalin oral solution should be prescribed only for patients who find it difficult to or are unable to swallow tablets.</p>	Included on the Grampian Joint Formulary for the indication in question; restricted use	19/06/2012
racecadotril 100mg capsules (Hidrasec®)	<a href="#">832/12</a>	Symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible.	Not recommended for use within NHS Scotland	18/12/2012



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ranibizumab 10mg/mL solution for injection (Lucentis®)	<a href="#">711/11</a>	Treatment of visual impairment due to diabetic macular oedema (DMO) in adults. <b>SMC restriction:</b> 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. Ranibizumab significantly improved visual acuity over 12 months compared with standard laser photocoagulation treatment. Open label extension results up to 3 years suggest maintenance of effect.	Included on the Grampian Joint Formulary for the indication in question; restricted use Updates decision 15/01/13	19/03/2013
ranolazine 375mg, 500mg, 750mg prolonged-release tablets (Ranexa®)	<a href="#">565/09</a>	As add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists).	Not recommended for use within NHS Scotland	20/11/2012
rifaximin 200mg film coated tablets (Xifaxanta®)	<a href="#">808/12</a>	Treatment of travellers' diarrhoea.	Not recommended for use within NHS Scotland	21/08/2012
rivaroxaban 15mg, 20mg film-coated tablets (Xarelto®)	<a href="#">852/13</a>	Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults.	Included on the Grampian Joint Formulary for the indication in question; restricted use	16/04/2013
rufinamide 40mg/mL oral suspension (Inovelon®)	<a href="#">795/12</a>	Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older. <b>SMC restriction:</b> restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.	Routinely available in line with local guidance	18/09/2012

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Sevikar HCT® film-coated tablets (olmesartan medoxomil/amlodipine besilate/hydrochlorothiazide)	<a href="#">823/12</a>	In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	15/01/2013
sildenafil (as citrate) 20mg film-coated tablets, 10mg/mL powder for oral solution (Revatio®)	<a href="#">809/12</a>	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. <b>SMC restriction:</b> restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question - because the medication is prescribed and supplied by the National Specialist Centre	18/12/2012
strontium ranelate 2g granules for oral suspension (Protelos®)	816/12	Treatment of osteoporosis in men at increased risk of fracture.	Not recommended for use within NHS Scotland, ADVISE ARCHIVED - This medicine is now withdrawn from use/discontinued.	16/10/2012

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
sugammadex 100mg/mL solution for injection (Bridion®)	<a href="#">527/09</a>	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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use Updates decision 16/04/13	16/07/2013
tadalafil 20mg film-coated tablets (Adcirca®)	<a href="#">710/11</a>	Adults for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity. <b>SMC restriction:</b> to initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question - because the medication is prescribed and supplied by the National Specialist Centre	17/07/2012
tadalafil 5mg film coated tablets (Cialis®)	<a href="#">849/12</a>	Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.	Not recommended for use within NHS Scotland	15/01/2013
Teysuno® 15mg/4.35mg/11.8mg, 20mg/5.8mg/15.8mg hard capsules (tegafur/gimeracil/oteracil)	<a href="#">802/12</a>	In adults for the treatment of advanced gastric cancer when given in combination with cisplatin. <b>SMC restriction:</b> to use in patients with advanced gastric cancer who are unsuitable for an anthracycline, fluorouracil and platinum triplet first-line regimen.	Included on the Grampian Joint Formulary for the indication in question; restricted use Updates decision 20/11/12	19/03/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
thiotepa 15mg, 100mg powder for concentrate for solution for infusion (Tepadina®)	<a href="#">790/12</a>	In combination with other chemotherapy medicinal products (1): with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients; (2): when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.	Not recommended for use within NHS Scotland	17/07/2012
tobramycin 28mg inhalation powder hard capsules (TOBI podhaler®)	783/12	For the suppressive therapy of chronic pulmonary infection due to <i>Pseudomonas aeruginosa</i> in adults and children aged 6 years and older with cystic fibrosis.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA276 Updates decision 16/10/12	16/04/2013
tocilizumab 20mg/mL concentrate for solution for infusion (RoActemra®)	774/12	Tocilizumab monotherapy in rheumatoid arthritis (RA) when biologic combination with methotrexate (MTX) is inappropriate [e.g. due to intolerance to MTX]. <b>SMC restriction:</b> tocilizumab is restricted for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA375 Updates decision 18/09/12	15/03/2016
tocofersolan 50mg/mL oral solution (Vedrop®)	<a href="#">696/11</a>	Vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region.	Not recommended for use within NHS Scotland	16/10/2012

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
triptorelin pamoate 11.25mg powder and solvent for suspension for injection (Salvacyl®)	<a href="#">796/12</a>	Reversible reduction of testosterone to castrate levels in order to decrease sexual drive in adult men with severe sexual deviations.	Not recommended for use within NHS Scotland	19/06/2012
ulipristal acetate 5mg tablets (Esmya®)	834/13	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.	The EMA has recommended that the marketing authorisation of the medicine be revoked. Updates decision 19/03/13	17/03/2020
vandetanib 100mg, 300mg film coated tablets (Caprelsa®)	<a href="#">797/12</a>	Treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease.	Not recommended for use within NHS Scotland	19/06/2012
velaglucerase alfa 400units powder for solution for infusion (Vpriv®)	<a href="#">681/11</a>	Long-term enzyme replacement therapy in patients with type 1 Gaucher disease.	Not included on the Grampian Joint Formulary because clinicians do not support the formulary inclusion; for the indication in question (because the incidence of Type 1 Gaucher disease is unpredictable and sporadic).	18/12/2012
vildagliptin 50mg tablets (Galvus®)	<a href="#">826/12</a>	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. <b>SMC restriction:</b> for use in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	19/02/2013
zonisamide 25mg, 50mg, 100mg hard capsules (Zonegran®)	<a href="#">817/12</a>	Monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy.	Not recommended for use within NHS Scotland	16/10/2012

# NHS Grampian Formulary Group decisions for SMC accepted medicines published April 2013 to March 2014



This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) accepted medicines published April 2013 to March 2014.

For the latest Formulary Group decisions see the [Grampian Medicines Management website](#).

**November 2021**

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NHS Grampian Formulary Group Decisions for SMC advice published April 2013 to March 2014

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
abatacept 125mg/mL solution for subcutaneous injection (Orencia®)	888/13	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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA375 Updates decision 17/09/13	15/03/2016
abatacept 250mg powder for concentrate for solution for infusion (Orencia®)	719/11	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a tumour necrosis factor (TNF)-alpha inhibitor. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA375 and TA715 Updates decision 16/04/13	15/03/2016

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®)	<a href="#">880/13</a>	For the 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. <b>SMC restriction:</b> prescribing by specialists in paediatric gastroenterology.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 20/08/13	19/08/2014
adalimumab 40mg solution for injection in pre-filled syringe or pen (Humira®)	858/13	For the treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (nr-axSpA) but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). Adalimumab should be prescribed in accordance with Assessment in Spondyloarthritis International Society (ASAS) guidance.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA383 Updates decision 16/04/13	15/03/2016



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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8ml solution for injection vial for paediatric use (Humira®)	881/13	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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA373 Updates decision 16/07/13	19/01/2016
afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®)	<a href="#">920/13</a>	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).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/03/14	17/06/2014
aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®)	<a href="#">878/13</a>	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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/03/14	20/05/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
aflibercept 40mg/mL solution for intravitreal injection (Eylea®)	<a href="#">857/13</a>	For the treatment of neovascular (wet) age-related macular degeneration (AMD).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/05/13	18/06/2013
argatroban 100mg/mL concentrate for solution for infusion (Exembol®)	<a href="#">812/12</a>	Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use	20/08/2013
aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®)	<a href="#">891/13</a>	Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. <b>SMC restriction:</b> restricted to initiation and management under the supervision of a child/adolescent psychiatrist.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/08/2014
atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg capsules (Strattera®)	<a href="#">909/13</a>	Treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	17/12/2013
axitinib 1mg, 5mg film-coated tablets (Inlyta®)	<a href="#">855/13</a>	For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/12/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
bortezomib 3.5mg powder for solution for injection (Velcade®)	<a href="#">927/13</a>	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. <b>SMC restriction:</b> use as triple therapy in combination with dexamethasone and thalidomide.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/01/14	18/02/2014
botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®)	<a href="#">916/13</a>	For the management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	19/11/2013
caffeine citrate 20mg/mL solution for infusion and oral solution (Peyona®)	<a href="#">814/12</a>	Treatment of primary apnoea of premature newborns.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	21/01/2014
calcium polystyrene sulphonate powder (Sorbisterit®)	<a href="#">890/13</a>	Treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	17/09/2013
canakinumab 150mg powder for solution for injection (Ilaris®)	<a href="#">882/13</a>	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above.	Not recommended for use within NHS Scotland	18/06/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
canakinumab 150mg powder for solution for injection (Ilaris®)	<a href="#">883/13</a>	Symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.	Not recommended for use within NHS Scotland	18/06/2013
canakinumab 150mg powder for solution for injection (Ilaris®)	<a href="#">926/13</a>	Treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.	Not recommended for use within NHS Scotland	19/11/2013
carglumic acid 200mg dispersible tablets (Carbaglu®)	<a href="#">899/13</a>	For the treatment of hyperammonaemia due to isovaleric acidaemia / hyperammonaemia due to methymalonic acidaemia / hyperammonaemia due to propionic acidaemia.	Included on the Grampian Joint Formulary for the indication in question; restricted use	19/11/2013
crizotinib 200mg and 250mg hard capsule (Xalkori®)	<a href="#">865/13</a>	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Included on the Grampian Joint Formulary for the indication in question; restricted use	19/11/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®)	<a href="#">799/12</a>	For 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. <b>SMC restriction:</b> In combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control.	Routinely available in line with national guidance, Updates decision 18/03/14	20/07/2021
darunavir 400mg, 800mg film-coated tablets, 100mg/mL oral suspension (Prezista®)	<a href="#">948/14</a>	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 <sup>3</sup> . <b>SMC restriction:</b> in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV.	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/03/2014
darunavir oral suspension 100mg/mL (Prezista®)	<a href="#">861/13</a>	Human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight. <b>SMC restriction:</b> in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV.	Included on the Grampian Joint Formulary for the indication in question; restricted use	16/04/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
deferasirox 125mg, 250mg, 500mg dispersible tablets (Exjade®)	<a href="#">866/13</a>	Treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.	Not recommended for use within NHS Scotland	16/04/2013
eltrombopag 25mg, 50mg, 75mg film-coated tablets (Revolade®)	<a href="#">919/13</a>	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.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	21/01/2014
enzalutamide 40mg soft capsules (Xtandi®)	<a href="#">911/13</a>	Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/12/2013
etravirine 25mg, 100mg, 200mg tablets (Intelence®)	<a href="#">901/13</a>	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. <b>SMC restriction:</b> to be prescribed under the supervision of specialists in paediatric HIV.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/11/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Eucreas® 50mg/850mg, 50mg/1000mg film-coated tablets (vildagliptin/metformin hydrochloride)	<a href="#">874/13</a>	Treatment of type 2 diabetes mellitus: - in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea - in triple combination therapy with insulin 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.	Not recommended for use within NHS Scotland	21/05/2013
everolimus 10mg tablets (Votubia®)	<a href="#">884/13</a>	Treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.	Not recommended for use within NHS Scotland	18/06/2013
fentanyl citrate 200micrograms, 400micrograms, 800micrograms buccal film (Breakyl®)	<a href="#">947/13</a>	Treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.	Not recommended for use within NHS Scotland	21/01/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
fluocinolone acetonide 190microgram intravitreal implant (Iluvien®)	<a href="#">864/13</a>	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. <b>SMC restriction:</b> - only in patients in whom the affected eye is pseudophakic (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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/02/14	18/03/2014
Ganfort® 0.3mg/mL / 5mg/mL preservative-free single-dose eye-drops (bimatoprost/timolol)	<a href="#">906/13</a>	For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. <b>SMC restriction:</b> to use in patients who have proven sensitivity to preservatives.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	19/11/2013
granisetron 3.1mg/24 hours transdermal patch (Sancuso®)	<a href="#">895/13</a>	In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult.	Included on the Grampian Joint Formulary for the indication in question, Updates decision 19/11/13	21/06/2016
imatinib 100mg, 400mg film coated tablets (Glivec®)	<a href="#">923/13</a>	Treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.	Not recommended for use within NHS Scotland	15/10/2013



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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
insulin glargine 100units/mL solution for injection in a vial, cartridge, pre-filled pen (Lantus® Clikstar®, Lantus® Solostar®)	<a href="#">860/13</a>	For the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. <b>SMC restriction:</b> patients in whom treatment with an insulin analogue is appropriate.	Included on the Grampian Joint Formulary for the indication in question; restricted use	16/04/2013
ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	<a href="#">779/12</a>	For the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/05/13	18/06/2013
ivacaftor 150mg film-coated tablets (Kalydeco®)	<a href="#">827/12</a>	For the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene.	Not recommended for use within NHS Scotland	18/06/2013
Komboglyze® 2.5mg/850mg, 2.5mg/1000mg film-coated tablets (saxagliptin/metformin)	<a href="#">870/13</a>	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 combination of saxagliptin and metformin as separate tablets. <b>SMC restriction:</b> 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.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	16/07/2013

NHS Grampian Formulary Group Decisions for SMC advice published April 2013 to March 2014

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Komboglyze® 2.5mg/850mg, 2.5mg/1000mg film-coated tablets (saxagliptin/metformin)	<a href="#">929/13</a>	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.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	21/01/2014
lapatinib 250mg film-coated tablets (Tyverb®)	<a href="#">925/13</a>	Treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.	Not recommended for use within NHS Scotland	19/11/2013
latanoprost 50microgram/mL preservative-free single-dose eye-drops (Monopost®)	<a href="#">879/13</a>	For the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. <b>SMC restriction:</b> to use in patients who have proven sensitivity to the preservative benzalkonium chloride.	Routinely available in line with local guidance Updates decision 20/08/13	16/11/2021
lenalidomide 2.5mg, 5mg, 10mg hard capsules (Revlimid®)	<a href="#">942/14</a>	For the 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/03/2014
levonorgestrel 1500microgram tablets (Upostelle®)	<a href="#">938/14</a>	Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.	Included on the Grampian Joint Formulary for the indication in question	18/02/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
linaclotide 290microgram hard capsules (Constella®)	<a href="#">869/13</a>	For the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults. <b>SMC restriction:</b> linaclotide is restricted for use in patients with moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 16/07/13	17/12/2013
lisdexamfetamine dimesylate 30mg, 50mg, 70mg capsules (Elvanse®)	<a href="#">863/13</a>	As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate.	Included on the Grampian Joint Formulary for the indication in question; restricted use	16/07/2013
lixisenatide 10microgram/0.2mL, 20microgram/0.2mL solution for injection in pre-filled disposable pen (Lyxumia®)	<a href="#">903/13</a>	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. <b>SMC restriction:</b> to use in patients for whom a glucagon-like protein-1 (GLP-1) agonist is appropriate, as an alternative to existing GLP-1 agonists.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/11/2013
lomitapide 5mg, 10mg, 20mg hard capsules (Lojuxta®)	<a href="#">956/14</a>	Adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis in adult patients with homozygous familial hypercholesterolaemia (HoFH).	Not recommended for use within NHS Scotland	18/02/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
mannitol 40mg inhalation powder hard capsule (Bronchitol®)	<a href="#">837/13</a>	Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/01/14	18/03/2014
medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press)	<a href="#">896/13</a>	For long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year.	Included on the Grampian Joint Formulary for the indication in question; pending protocol, Updates decision 15/10/13	16/08/2016
mirabegron 25mg, 50mg prolonged-release tablets (Betmiga®)	<a href="#">862/13</a>	For symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.	Routinely available in line with local guidance, Updates decision 18/06/13	21/02/2017
nalmefene 18mg film-coated tablets (Selincro®)	<a href="#">917/13</a>	For the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms, and who do not require immediate detoxification.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 19/11/13	17/03/2015

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
ondansetron 4mg, 8mg orodispersible films (Setofilm®)	<a href="#">912/13</a>	<p>In adults:</p> <ul style="list-style-type: none"> <li>- Prophylaxis of acute nausea and vomiting (NV) induced by moderately emetogenic chemotherapy.</li> <li>- Prophylaxis and treatment of delayed NV induced by moderately to highly emetogenic chemotherapy.</li> <li>- Prophylaxis and treatment of acute and delayed NV induced by highly emetogenic radiotherapy.</li> <li>- Prophylaxis and treatment of post-operative NV (PONV).</li> </ul> <p>In paediatrics:</p> <ul style="list-style-type: none"> <li>- Management of chemotherapy-induced NV in children aged <math>\geq 6</math> months.</li> <li>- Prophylaxis and treatment of PONV in children aged <math>\geq 4</math> years.</li> </ul> <p><b>SMC restriction:</b> ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing.</p> <p>Generic preparations of ondansetron are available at a lower cost than the proprietary products.</p>	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question, Updates decision 17/12/13	21/06/2016
pegylated interferon alpha-2a 90microgram, 135microgram and 180microgram pre-filled syringe, 135microgram and 180microgram pre-filled pen (Pegasys®)	871/13	<p>In combination with ribavirin, for the treatment of chronic hepatitis C in treatment-naïve children and adolescents, 5 years of age and older, who are positive for serum HCV-RNA.</p> <p><b>SMC restriction:</b> prescribing by specialist in paediatric infectious disease or paediatric gastroenterology.</p>	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA300 Updates decision 16/07/13	18/02/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
pirfenidone 267mg capsule (Esbriet®)	<a href="#">835/13</a>	In adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). <b>SMC restriction:</b> For use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/09/13	19/11/2013
raltegravir 25mg, 100mg chewable tablets, 400mg film-coated tablets (Isentress®)	<a href="#">902/13</a>	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. <b>SMC restriction:</b> to 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 should to be prescribed under the supervision of specialists in paediatric HIV. The chewable and film-coated tablets are not bioequivalent and therefore are not interchangeable.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/11/2013
ranibizumab 10mg/mL solution for injection (Lucentis®)	<a href="#">732/11</a>	For the treatment of visual impairment due to macular oedema (MO) secondary to branch retinal vein occlusion (BRVO) in adults. SMC has previously accepted ranibizumab for use in macular oedema secondary to CRVO. This advice now extends its use to patients with BRVO.	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/06/2013
ranibizumab 10mg/mL solution for injection (Lucentis®)	<a href="#">907/13</a>	Treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/12/2013

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
rifaximin 550mg film-coated tablets (Targaxan®)	<a href="#">893/13</a>	Reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/09/2013
rituximab 100mg, 500mg solution for infusion (MabThera®)	<a href="#">894/13</a>	In combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). <b>SMC restriction:</b> to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/11/2013
saxagliptin 2.5mg, 5mg film-coated tablets (Onglyza®)	<a href="#">918/13</a>	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. <b>SMC restriction:</b> as an alternative dipeptidyl peptidase-4 inhibitor option.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	17/12/2013
saxagliptin 2.5mg, 5mg film-coated tablets (Onglyza®)	<a href="#">958/14</a>	Monotherapy in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.	Not recommended for use within NHS Scotland	18/03/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
sodium phenylbutyrate granules 483mg/g (Pheburane®)	<a href="#">914/13</a>	Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	17/12/2013
Stribild® 150mg/150mg/200mg/245mg film-coated tablets (elvitegravir/cobicistat/tenofovir disoproxil (as fumarate))	<a href="#">887/13</a>	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®.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/09/2013
tafamidis meglumine 20mg soft capsules (Vyndaqel®)	<a href="#">877/13</a>	Treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment.	Not recommended for use within NHS Scotland	21/05/2013
tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tablets (Viread®)	<a href="#">900/13</a>	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. <b>SMC restriction:</b> to be prescribed under the supervision of specialists in paediatric infectious diseases.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/11/2013



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tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Viread®)	<a href="#">904/13</a>	<p><i>HIV-1 infection</i> - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to &lt; 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents.</p> <p><i>Hepatitis B infection</i> - for the treatment of chronic hepatitis B in adolescents aged 12 to &lt;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.</p> <p><b>SMC restriction:</b> to be prescribed under the supervision of specialists in paediatric infectious diseases.</p>	<p>Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13</p>	19/11/2013

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tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®)	<a href="#">905/13</a>	<p><i>HIV-1</i> - in combination with other antiretrovirals for the treatment of HIV 1 infected paediatric patients, with NRTI resistance or toxicities precluding the use of first line agents, from 2 to &lt; 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretrovirals for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate.</p> <p><i>Hepatitis B</i> - (12 years and over ) chronic hepatitis B for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis; (adults) decompensated liver disease.</p> <p><b>SMC restriction:</b> &lt;18 years, under the supervision of specialists in paediatric infectious diseases.</p>	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/10/13	19/11/2013
teriflunomide 14mg film-coated tablets (Aubagio®)	<a href="#">940/14</a>	<p>Treatment of adults with relapsing remitting multiple sclerosis (MS).</p> <p><b>SMC restriction:</b> 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.</p>	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/03/14	15/04/2014
timolol 1mg/g eye gel for single-dose container (Tiopex®)	<a href="#">941/14</a>	<p>Reduction of the elevated intraocular pressure in patients with:</p> <ul style="list-style-type: none"> <li>- ocular hypertension,</li> <li>- chronic open angle glaucoma.</li> </ul> <p><b>SMC restriction:</b> to use in patients who have proven sensitivity to preservatives.</p>	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/02/14	18/03/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
timothy grass pollen allergen 75,000 SQ-T oral lyophilisate (GRAZAX®)	<a href="#">868/13</a>	Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.	Not recommended for use within NHS Scotland	16/04/2013
tocilizumab 20mg/mL concentrate for infusion (RoActemra®)	930/13	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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA373 Updates decision 21/01/14	19/01/2016
trastuzumab 600mg/5mL solution for injection (Herceptin®)	<a href="#">928/13</a>	Treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (see DAD for full details of licensed indication). <b>SMC restriction:</b> 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).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/01/14	18/03/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®)	<a href="#">889/13</a>	For the dissolution of cholesterol gallstones in the gall bladder. (The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s).) For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	17/09/2013
ustekinumab 45mg solution for injection in pre-filled syringe (Stelara®)	<a href="#">944/14</a>	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. <b>SMC restriction:</b> for use in patients with active psoriatic arthritis who have failed on, or are unsuitable for, treatment with an anti-TNF drug.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/03/14	16/09/2014
vemurafenib 240mg film-coated tablets (Zelboraf®)	<a href="#">792/12</a>	As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. <b>SMC restriction:</b> for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma.	Not routinely available as there is a local preference for alternative medicines, Updates decision 21/01/14	18/08/2020
Vesomni® 6mg/0.4mg modified release tablets (solifenacin succinate/tamsulosin hydrochloride)	<a href="#">945/14</a>	For the 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/03/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
vildagliptin 50mg tablets (Galvus®)	<a href="#">875/13</a>	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. <b>SMC restriction:</b> as an alternative dipeptidyl peptidase-4 inhibitor option.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	17/12/2013
vismodegib 150mg hard capsules (Erivedge®)	<a href="#">924/13</a>	Treatment of adult patients with: - symptomatic metastatic basal cell carcinoma - locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy	Not recommended for use within NHS Scotland	15/10/2013
Voractiv® 150mg/75mg/400mg/275mg film-coated tablets (rifampicin/isoniazid/pyrazinamide/ethambutol hydrochloride)	<a href="#">876/13</a>	Initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines.	Not recommended for use within NHS Scotland	21/05/2013
Zoely® 2.5mg/1.5mg film-coated tablets (norgestrel acetate/estradiol)	<a href="#">898/13</a>	Oral contraception.	Not recommended for use within NHS Scotland	16/07/2013
zonisamide 25mg, 50mg, 100mg capsules (Zonegran®)	<a href="#">949/14</a>	As adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above. <b>SMC restriction:</b> on advice from specialists (paediatric neurologists or paediatricians with an expertise in epilepsy).	Included on the Grampian Joint Formulary for the indication in question; restricted use	18/03/2014

# NHS Grampian Formulary Group Decisions for SMC advice published April 2014 to March 2015



This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) advice published April 2014 to March 2015.

For the latest Formulary Group decisions see the [Grampian Medicines Management website](#).

**November 2021**

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
aflibercept 40mg/mL solution for injection (Eylea®)	<a href="#">954/14</a>	For adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/04/14	20/05/2014
aflibercept 40mg/mL solution for injection (Eylea®)	<a href="#">1003/14</a>	For adults for the treatment of visual impairment due to diabetic macular oedema (DMO). <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/11/14	16/12/2014
alemtuzumab 12mg concentrate for solution for infusion (Lemtrada®)	<a href="#">959/14</a>	For adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/07/14	19/08/2014
alogliptin 6.25mg, 12.5mg, 25mg film-coated tablets (Vipidia®)	<a href="#">937/14</a>	See SMC advice for indications.	Routinely available in line with local guidance Updates decision 21/10/14	20/11/2018
Anoro® Ellipta® 55micrograms/22micrograms inhalation powder pre-dispensed (umeclidinium/vilanterol)	<a href="#">978/14</a>	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	Included on the Grampian Joint Formulary for the indication in question, Updates decision 17/02/15	20/10/2015
apixaban 2.5mg, 5mg film-coated tablets (Eliquis®)	<a href="#">1029/15</a>	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults.	Included on the Grampian Joint Formulary for the indication in question, Updates decision 17/03/15	21/07/2015

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
aripiprazole 400mg powder and solvent for prolonged release suspension for injection (Abilify Maintena®)	<a href="#">962/14</a>	Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 20/05/14	19/08/2014
azithromycin 500mg powder for solution for infusion (Zedbac®)	<a href="#">950/14</a>	The treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	15/04/2014
aztreonam lysine 75mg powder and solvent for nebuliser solution (Cayston®)	<a href="#">753/12</a>	Suppressive therapy of chronic pulmonary infections due to <i>Pseudomonas aeruginosa</i> in patients with cystic fibrosis aged six years and older. <b>SMC restriction:</b> when inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit (measured as $\geq 2\%$ decline in forced expiratory volume in 1 second [FEV1]).	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	20/01/2015
bosutinib 100mg, 500mg film-coated tablets (Bosulif®)	<a href="#">910/13</a>	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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/02/15	19/05/2015



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botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®)	<a href="#">931/13</a>	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. <b>SMC restriction:</b> patients who have failed appropriate oral treatment options.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/07/14	18/11/2014
botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®)	<a href="#">986/14</a>	Focal lower limb spasticity, including the treatment of ankle disability due to lower limb spasticity associated with stroke in adults.	Not recommended for use within NHS Scotland	15/07/2014
brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®)	<a href="#">845/12</a>	<b>SMC restriction:</b> treatment of adult patients with relapsed or refractory CD30 positive 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/10/14	17/02/2015
brimonidine 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®)	<a href="#">1016/14</a>	The symptomatic treatment of facial erythema of rosacea in adult patients. <b>SMC restriction:</b> for use in patients with moderate to severe persistent facial erythema associated with rosacea.	Included on the Grampian Joint Formulary for the indication in question, Updates decision 20/01/15	17/02/2015
budesonide 9mg gastro-resistant granules (Budenofalk®)	<a href="#">970/14</a>	Induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/06/14	19/08/2014
cabozantinib 20mg, 80mg hard capsules (Cometriq®)	<a href="#">1022/15</a>	For the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma.	Not recommended for use within NHS Scotland	17/03/2015

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
canagliflozin 100mg, 300mg film-coated tablets (Invokana®)	<a href="#">963/14</a>	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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/06/14	15/07/2014
capsaicin 179mg cutaneous patch (Qutenza®)	<a href="#">673/11</a>	For the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. <b>SMC restriction:</b> to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments.	Routinely available in line with local guidance Updates decision 21/10/14	18/12/2018
certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®)	960/14	For the treatment of adult patients with severe active axial spondyloarthritis.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA375 Updates decision 20/05/14	15/03/2016

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®)	973/14	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. <b>SMC restriction:</b> use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA445 Updates decision 15/07/14	16/09/2014
cetuximab 100mg/20mL, 500mg/100mL solution for infusion (Erbitux®)	1012/14	Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer: <ul style="list-style-type: none"> <li>• in combination with irinotecan-based chemotherapy;</li> <li>• in first-line in combination with FOLFOX.</li> </ul> <b>SMC restriction:</b> 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).	Routinely available in line with regional guidance, Advice superseded by NICE TA439 Updates decision 20/01/15	18/04/2017
cobicistat 150mg film-coated tablets (Tybost®)	<a href="#">933/13</a>	Pharmacokinetic enhancer of atazanavir 300mg once daily or darunavir 800mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults.	Not recommended for use within NHS Scotland	20/05/2014
colecalciferol 25,000 international units oral solution (InVita D3®)	<a href="#">1011/14</a>	The prevention and treatment of vitamin D deficiency.	Included on the Grampian Joint Formulary for the indication in question	16/12/2014

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colestilan 1g film-coated tablets, 2g, 3g granules sachet (BindRen®)	939/14	For the treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	Not recommended for use within NHS Scotland. On 1 April 2015, the marketing authorisation for BindRen was withdrawn at the request of the marketing authorisation holder.	17/02/2015
dabigatran etexilate 110mg, 150mg capsules (Pradaxa®)	<a href="#">995/14</a>	For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	21/10/2014
dabrafenib 50mg, 75mg hard capsules (Tafinlar®)	<a href="#">1023/15</a>	Monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. <b>SMC restriction:</b> for use in patients with unresectable or metastatic BRAF V600 mutation-positive metastatic melanoma who have received no prior therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/03/2015
daclatasvir 30mg, 60mg film-coated tablets (Daklinza®)	1002/14	In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults. <b>SMC restriction:</b> use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis.	This medicine is now withdrawn from use/discontinued, Updates decision 18/11/14	15/03/2019

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dapagliflozin 5mg, 10mg film-coated tablet (Forxiga®)	<a href="#">799/12</a>	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. <b>SMC restriction:</b> in triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor.	Routinely available in line with national guidance, Updates decision 15/07/14	20/07/2021
dapoxetine hydrochloride 30mg, 60mg film-coated tablets (Priligy®)	<a href="#">987/14</a>	Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.	Not recommended for use within NHS Scotland	15/07/2014
defibrotide 80mg/mL concentrate for solution for infusion (Defitelio®)	<a href="#">967/14</a>	Treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/06/14	15/07/2014
denosumab 60mg solution for injection in a pre-filled syringe (Prolia®)	1013/14	Osteoporosis in men at increased risk of fractures	Not recommended for use within NHS Scotland, ADVICE ARCHIVED	18/11/2014
dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®)	<a href="#">886/13</a>	Treatment of adult patients with relapsing remitting multiple sclerosis.	Included on the Grampian Joint Formulary for the indication in question; restricted use	15/04/2014
dolutegravir 50mg film-coated tablets (Tivicay®)	<a href="#">961/14</a>	In combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age.	Included on the Grampian Joint Formulary for the indication in question; restricted use	20/05/2014

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Dymista® nasal spray 137micrograms/50micrograms per actuation nasal spray (azelastine hydrochloride/fluticasone propionate)	<a href="#">921/13</a>	For the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/10/14	19/05/2015
empagliflozin 10mg, 25mg tablets (Jardiance®)	<a href="#">993/14</a>	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. <b>SMC restriction:</b> 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	Included on the Grampian Joint Formulary for the indication in question; pending protocol, Updates decision 21/10/14	21/06/2016
Epiduo® 0.1%/2.5% gel (adapalene/benzoyl peroxide)	<a href="#">682/11</a>	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. <b>SMC restriction:</b> the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate.	Included on the Grampian Joint Formulary for the indication in question, Updates decision 15/04/14	21/07/2015
everolimus 2.5mg, 5mg, 10mg tablets (Afinitor®)	<a href="#">595/10</a>	The treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/11/14	16/12/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Eviplera® 25mg/200mg/245mg tablets (rilpivirine/emtricitabine/tenofovir disoproxil (as fumarate))	<a href="#">951/14</a>	Treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load $\leq 100,000$ 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®.	Included on the Grampian Joint Formulary for the indication in question; restricted use	15/04/2014
fingolimod 0.5mg hard capsules (Gilenya®)	<a href="#">992/14</a>	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. <b>SMC restriction:</b> for use in patients with rapidly evolving severe relapsing remitting multiple sclerosis.	Included on the Grampian Joint Formulary for the indication in question; restricted use	21/10/2014

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
follitropin alfa 75units, 150units, 225units, 300units, 450units pre-filled pen for subcutaneous injection (Bemfola®)	<a href="#">1025/15</a>	<p>In adult women for:</p> <ul style="list-style-type: none"> <li>- anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate;</li> <li>- stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer;</li> <li>- 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 &lt;1.2 units/L.</li> </ul> <p>In adult men for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human chorionic gonadotrophin (hCG) therapy.</p>	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	17/02/2015
fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt®)	<a href="#">1033/15</a>	<p>For the treatment of the following infections in adults and children including neonates:</p> <ul style="list-style-type: none"> <li>- Acute osteomyelitis</li> <li>- Complicated urinary tract infections</li> <li>- Nosocomial lower respiratory tract infections</li> <li>- Bacterial meningitis</li> <li>- Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above</li> </ul> <p><b>SMC restriction:</b> initiation by microbiologists or infectious disease specialists.</p>	<p>Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/03/15</p>	21/04/2015



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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Fostair® 100micrograms/6micrograms metered dose inhaler (beclometasone dipropionate/formoterol fumarate dihydrate)	<a href="#">976/14</a>	Symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	Included on the Grampian Joint Formulary for the indication in question	15/07/2014
golimumab 50mg, 100mg solution for injection (Simponi®)	946/13	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA329 Updates decision 21/10/14	17/03/2015
Harvoni® 90mg/400mg film-coated tablet (ledipasvir/sofosbuvir)	<a href="#">1030/15</a>	Treatment of chronic hepatitis C (CHC) in adults. <b>SMC restriction:</b> genotype 1 and 4 CHC only.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/03/2015
idelalisib 100mg, 150mg tablets (Zydelig®)	<a href="#">1026/15</a>	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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/03/15	19/05/2015

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
infliximab 100mg powder for concentrate for solution for infusion (Inflectra®)	1007/14	<p><b>SMC restriction:</b> Infliximab (Inflectra®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®].</p> <p>Infliximab (Inflectra®) is a biosimilar product to a reference product (infliximab [Remicade®]). The British National Formulary advises that it is good practice to prescribe biologic medicinal products by brand name.</p>	<p>Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA375 Updates decision 17/03/15</p>	15/03/2016
infliximab 100mg powder for concentrate for solution for infusion (Remicade®)	374/07	<p>Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.</p>	<p>Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA329 Updates decision 20/05/14</p>	17/03/2015
infliximab 100mg powder for concentrate for solution for infusion (Remsima®)	1006/14	<p><b>SMC restriction:</b> Infliximab (Remsima®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®].</p> <p>Infliximab (Remsima®) is a biosimilar product to a reference product (infliximab [Remicade®]). The British National Formulary advises that it is good practice to prescribe biologic medicinal products by brand name.</p>	<p>Included on the Grampian Joint Formulary for the indication in question; restricted use, Advice superseded by NICE TA375 Updates decision 17/03/15</p>	15/03/2016

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ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	<a href="#">997/14</a>	Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use).	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/11/14	17/03/2015
lenalidomide 5mg, 10mg, 15mg, 25mg hard capsules (Revlimid®)	<a href="#">441/08</a>	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). <b>SMC restriction:</b> to use at first relapse in patients who have received prior therapy with bortezomib in whom thalidomide has not been tolerated or is contraindicated.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/04/14	20/05/2014
lipegfilgrastim 6mg solution for injection (Lonquex®)	<a href="#">908/13</a>	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). <b>SMC restriction:</b> where a long-acting granulocyte-colony-stimulating factor is appropriate.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 15/04/14	16/02/2016
lubiprostone 24micrograms soft capsules (Amitiza®)	977/14	The treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures (e.g. educational measures, physical activity) are inappropriate.	This medicine is now withdrawn from use/discontinued Updates decision 19/08/14	21/07/2020

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lurasidone 18.5mg, 37mg, 74mg film-coated tablets (Latuda®)	<a href="#">994/14</a>	For the treatment of schizophrenia in adults aged 18 years and over. <b>SMC restriction:</b> as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/10/14	16/02/2016
macitentan 10mg film-coated tablets (Opsumit®)	<a href="#">952/14</a>	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. <b>SMC restriction:</b> to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or similar specialists.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question - because the medication is prescribed and supplied by the National Specialist Centre	15/04/2014
mifepristone 200mg tablets, misoprostol 0.2mg vaginal tablets combipack (Medabon®)	<a href="#">913/13</a>	For medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 18/11/14	20/01/2015
misoprostol 200microgram vaginal delivery system (Mysodelle®)	996/14	For the induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.	This medicine is now withdrawn from use/discontinued, Updates decision 21/10/14	19/01/2021
natalizumab 300mg concentrate for solution for infusion (Tysabri®)	<a href="#">979/14</a>	Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate.	Not recommended for use within NHS Scotland	17/06/2014

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obinutuzumab 1000mg concentrate for solution for infusion (Gazyvaro®)	<a href="#">1008/14</a>	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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 16/12/14	17/02/2015
ocriplasmin 0.5mg/0.2mL concentrate for solution for injection (Jetrea®)	<a href="#">892/13</a>	In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. <b>SMC restriction:</b> 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).	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	19/08/2014
olodaterol 2.5microgram solution for inhalation (Striverdi® Respimat®)	<a href="#">974/14</a>	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	20/01/2015
omalizumab 150mg solution for injection (Xolair®)	<a href="#">1017/14</a>	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. <b>SMC restriction:</b> 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	20/01/2015

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paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®)	<a href="#">968/14</a>	In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	17/02/2015
peginterferon beta-1a 63, 94, 125microgram solution for injection in pre-filled syringe (Plegridy®)	<a href="#">1018/14</a>	In adult patients for the treatment of relapsing remitting multiple sclerosis.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 20/01/15	17/03/2015
pemetrexed 100mg, 500mg powder for concentrate for solution for infusion (Alimta®)	<a href="#">770/12</a>	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.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	16/12/2014
Pliaglis® 70mg/g / 70mg/g cream (tetracaine/lidocaine)	1000/14	Local dermal anaesthesia on intact skin prior to dermatological procedures in adults.	This medicine is now withdrawn from use/discontinued Updates decision 21/10/14	20/06/2017
pomalidomide 1mg, 2mg, 3mg, 4mg hard capsules (Imnovid®)	<a href="#">972/14</a>	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.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 16/12/14	20/01/2015

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
posaconazole 100mg gastro-resistant tablets (Noxafil®)	<a href="#">999/14</a>	See SMC advice for indications. <b>SMC restriction:</b> to patients in whom there is a specific risk of <i>Aspergillus</i> infection or where fluconazole or itraconazole are not tolerated on the advice of local microbiologists or specialists in infectious diseases.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 21/10/14	20/01/2015
racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants®, Hidrasec Children®)	<a href="#">818/12</a>	Complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition and when causal treatment is not possible. If causal treatment is possible racecadotril can be administered as a complementary treatment.	Not recommended for use within NHS Scotland	19/08/2014
Relvar® Ellipta® 92micrograms/22micrograms inhalation powder (fluticasone furoate/vilanterol)	<a href="#">953/14</a>	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. <b>SMC restriction:</b> in patients with severe COPD (FEV1 <50% predicted normal).	Included on the Grampian Joint Formulary for the indication in question, Updates decision 15/04/14	15/07/2014
Relvar® Ellipta® 92micrograms/22micrograms, 184micrograms/22micrograms inhalation powder (fluticasone furoate/vilanterol)	<a href="#">966/14</a>	For the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists.	Included on the Grampian Joint Formulary for the indication in question; pending protocol, Updates decision 17/06/14	19/01/2016

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®)	<a href="#">1001/14</a>	<p>Chronic thromboembolic pulmonary hypertension (CTEPH): Treatment of adult patients with World Health Organisation (WHO) functional class II to III with:</p> <ul style="list-style-type: none"> <li>• inoperable CTEPH,</li> <li>• persistent or recurrent CTEPH after surgical treatment,</li> </ul> <p>to improve exercise capacity.</p> <p><b>SMC restriction:</b> 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.</p>	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question - because the medication is prescribed and supplied by the National Specialist Centre	16/12/2014
rituximab 1400mg solution for subcutaneous injection (Mabthera®)	<a href="#">975/14</a>	<p>For non-Hodgkin lymphoma (NHL) in adults:</p> <ul style="list-style-type: none"> <li>- previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy;</li> <li>- maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy;</li> <li>- treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.</li> </ul> <p><b>SMC restriction:</b> 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.</p>	<p>Included on the Grampian Joint Formulary for the indication in question;</p> <p>restricted use,</p> <p>Updates decision 15/07/14</p>	17/02/2015



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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
ruxolitinib (as phosphate) 5mg, 15mg, 20mg tablets (Jakavi®)	<a href="#">867/13</a>	The treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 17/03/15	19/05/2015
saxagliptin 2.5mg, 5mg film-coated tablets (Onglyza®)	<a href="#">772/12</a>	In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	18/11/2014
Simbrinza® 10mg/mL/2mg/mL eye drops suspension (brinzolamide/brimonidine tartrate)	<a href="#">991/14</a>	Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question	18/11/2014
simeprevir 150mg hard capsules (Olysio®)	988/14	In combination with other medicinal products for the treatment of chronic hepatitis C in adult patients.	This medicine is now withdrawn from use in the European Union Updates decision 21/10/14	15/05/2018

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sofosbuvir 400mg tablets (Sovaldi®)	<a href="#">964/14</a>	In combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. <b>SMC restriction:</b> sofosbuvir is accepted for use in patients with genotypes 1 to 6. Use in treatment-naive patients with genotype 2 is restricted to 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.	Included on the Grampian Joint Formulary for the indication in question; restricted use	17/06/2014
telavancin hydrochloride 250mg, 750mg powder for concentrate for solution for infusion (Vibativ®)	<a href="#">1015/14</a>	Treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant <i>Staphylococcus aureus</i> (MRSA).	Not recommended for use within NHS Scotland	18/11/2014

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tocilizumab 162mg solution for injection in pre-filled syringe (RoActemra®)	<a href="#">982/14</a>	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. <b>SMC restriction:</b> tocilizumab is restricted to use in accordance with current eligibility and continuation rules for biologic therapies in rheumatoid arthritis.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 19/08/14	16/09/2014
tocilizumab 20mg/mL concentrate for solution for infusion (RoActemra®)	<a href="#">1020/14</a>	Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.	Not recommended for use within NHS Scotland	16/12/2014
Treclin® 1%/0.025% gel (clindamycin/tretinoin)	<a href="#">1010/14</a>	For the topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older.	Included on the Grampian Joint Formulary for the indication in question, Updates decision 16/12/14	21/07/2015
Triumeq® 50mg/600mg/300mg film-coated tablets (dolutegravir/abacavir/ lamivudine)	<a href="#">1009/14</a>	For the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40kg.	Included on the Grampian Joint Formulary for the indication in question; restricted use, Updates decision 16/12/14	20/01/2015

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Ultibro® Breezhaler® 85micrograms/43micrograms inhalation powder hard capsules (equivalent to 110microgram indacaterol and 50microgram glycopyrronium)	<a href="#">922/13</a>	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Not included on the Grampian Joint Formulary because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary, Updates decision 16/12/14	20/10/2015
umeclidinium 55micrograms powder for inhalation (Incruse®)	<a href="#">1004/14</a>	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	Included on the Grampian Joint Formulary for the indication in question, Updates decision 16/12/14	20/10/2015
Vipdomet® 12.5mg/1000mg film- coated tablets (alogliptin/metformin)	<a href="#">998/14</a>	See SMC advice for indications.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	21/10/2014
Vokanamet® 50mg/850mg, 50mg/1000mg immediate release tablets (canagliflozin/metformin)	<a href="#">1019/14</a>	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control. <b>SMC restriction:</b> use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy.	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question, Updates decision 20/01/15	17/02/2015
voriconazole 50mg, 200mg film- coated tablets, 200mg powder for solution for infusion, 200mg powder and solvent for solution for infusion, 40mg/ml powder for oral suspension (Vfend®)	<a href="#">1014/14</a>	Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients.	Not recommended for use within NHS Scotland	18/11/2014

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Xigduo® 5mg/850mg, 5mg/1000mg film-coated tablets (dapagliflozin/metformin)	<a href="#">983/14</a>	<p>In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:</p> <p><b>SMC restriction:</b> to use in patients for whom a combination of dapagliflozin and metformin is an appropriate choice of therapy i.e.</p> <ul style="list-style-type: none"> <li>- when metformin alone does not provide adequate glycaemic control and a sulphonylurea is inappropriate.</li> <li>- in combination with insulin, when insulin and metformin does not provide adequate control.</li> <li>- in combination with a sulphonylurea, when a sulphonylurea and metformin does not provide adequate control.</li> </ul>	Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question	19/08/2014