NHS Grampian
Formulary Group Decisions for SMC advice published April 2018 to March 2019

This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) advice published April 2018 to March 2019.

For the latest Formulary Group decisions see the Grampian Area Formulary website.

December 2023

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
alectinib 150mg hard capsules (Alecensa®)	2012	As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Routinely available in line with national guidance, SMC 2012 https://www.scottishmedicines.org.uk/media/3645/alectinib-hydrochloride-alecensa-final-july-2018-for-website.pdf Updates decision 21/08/18	18/09/2018
anakinra 100mg/0.67mL solution for injection in prefilled syringe (150mg/mL) (Kineret®)	2104	In adults, adolescents, children and infants aged eight months and older with a body weight of 10kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs).	Routinely available in line with national guidance, SMC 2104 https://www.scottishmedicines.org.uk/media/3764/anakinra-kineret-final-sept-2018-amended-021018-for-website.pdf Updates decision 16/10/18	17/09/2019
asparaginase 10,000units powder for concentrate for solution for infusion (Spectrila®)	1319/18	As a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adults.	Routinely available in line with national guidance, SMC 1319/18 https://www.scottishmedicines.org.uk/media/3274/asparaginase-spectrila-abbreviated-final-march-2018-for-website.pdf	17/04/2018
atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®)	2103	As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2103 https://www.scottishmedicines.org.uk/media/3850/atezolizumab-tecentriq-final-oct-2018.pdf	20/11/2018

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atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®)	1336/18	As monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (EGFR) activating mutations or anaplastic lymphoma kinase (ALK)-positive tumour mutations should also have received targeted therapy before receiving atezolizumab. **SMC restriction:** treatment with atezolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 1336/18 https://www.scottishmedicines.org.uk/media/3554/atezolizumab-tecentriq-final-june-2018-for-website.pdf Updates decision 17/07/18	20/11/2018
avelumab 20mg/mL concentrate for solution for infusion (Bavencio®)	1315/18	As monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (mMCC).	Routinely available in line with national guidance, SMC 1315/18 https://www.scottishmedicines.org.uk/media/3410/avelumab-bavencio-final-april-2018-for-website.pdf	15/05/2018
Biktarvy® 50mg/200mg/25mg film-coated tablets (bictegravir/ emtricitabine/ tenofovir alafenamide)	2093	Treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.	Routinely available in line with national guidance, SMC 2093 https://www.scottishmedicines.org.uk/media/3687/bictegravir-biktarvy-final-august-2018-amended-310818-for-website.pdf Updates decision 18/09/18	20/11/2018
bosutinib 100mg, 400mg, 500mg film-coated tablets (Bosulif®)	2109	Treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukaemia.	Not routinely available as not recommended for use in NHS Scotland, SMC 2109 https://www.scottishmedicines.org.uk/media/3646/bosutinib-bosulif-non-sub-final-july-2018-for-website.pdf	21/08/2018
brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®)	2085	Treatment of adult patients with CD30+ Hodgkin lymphoma at increased risk of relapse or progression following autologous stem cell transplant.	Not routinely available as not recommended for use in NHS Scotland, SMC 2085 https://www.scottishmedicines.org.uk/media/3403/brentuximab-vedotin-adcetris-non-sub-final-april-2018-for-website.pdf	15/05/2018

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brivaracetam, 10mg, 25mg, 50mg, 75mg, 100mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®)	2113	Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from 4 years to <16 years of age with refractory epilepsy. **SMC restriction:** treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	Routinely available in line with national guidance, SMC 2113 https://www.scottishmedicines.org.uk/media/3956/brivaractetam-briviact-abb-final-nov-2018-for-website.pdf	18/12/2018
brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®)	1283/17	For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. **SMC restriction:** for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	Routinely available in line with national guidance, SMC 1283/17 https://www.scottishmedicines.org.uk/media/3404/brodalumab-kyntheum-resubmission-final-april-2018-amended-240418-for-website.pdf Updates decision 15/05/18	21/08/2018
cabozantinib 20mg, 40mg, 60mg film-coated tablets (Cabometyx®)	2136	Advanced renal cell carcinoma (RCC) in treatment-naïve adults with intermediate or poor risk.	Not routinely available as not recommended for use in NHS Scotland, SMC 2136 https://www.scottishmedicines.org.uk/media/4123/cabozantinib-cabometyx-resubmission-final-jan-2019-for-website.pdf	19/02/2019
cabozantinib 20mg, 40mg, 60mg film-coated tablets (Cabometyx®)	2160	As monotherapy for the treatment of hepatocellular carcinoma in adults who have previously been treated with sorafenib.	Not routinely available as not recommended for use in NHS Scotland, SMC 2160 https://www.scottishmedicines.org.uk/media/4165/cabozantinib-cabometyx-non-sub-final-jan-2019-for-website.pdf	19/02/2019
cenegermin 20micrograms/mL eye drops, solution (Oxervate®)	2124	Treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults.	This medicine is now withdrawn from use/discontinued, Updates decision 16/10/18	19/05/2020

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ceritinib 150mg hard capsules (Zykadia®)	1333/18	As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer.	Not routinely available as not recommended for use in NHS Scotland, SMC 1333/18 https://www.scottishmedicines.org.uk/media/3275/ceritinib-zykadia-non-sub-final-march-2018-for-website.pdf	17/04/2018
ciclosporin 1mg/mL (0.1%) eye drops emulsion (Verkazia®)	2111	Treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.	Routinely available in line with national guidance, SMC 2111 https://www.scottishmedicines.org.uk/media/3957/ciclosporin-verkazia-final-nov-2018-for-website.pdf Updates decision 18/12/18	15/09/2020
ciprofloxacin 2mg/mL ear drops solution (Cetraxal®)	1320/18	Treatment of acute otitis externa in adults and children older than 1 year with an intact tympanic membrane, caused by ciprofloxacin susceptible microorganisms. **SMC restriction:** when off-label or unlicensed ciprofloxacin formulations would otherwise be used.	Routinely available in line with local guidance, SMC 1320/18 https://www.scottishmedicines.org.uk/media/3276/ciprofloxacin-eardrops-cetraxal-abbreviated-final-march-2018-for-website.pdf Updates decision 17/04/18	19/03/2019
conestat alfa 2,100units powder (and solvent) for solution for injection (Ruconest®)	745/11	Treatment of acute angioedema attacks in adults and adolescents with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.	Routinely available in line with national guidance, SMC 745/11 https://www.scottishmedicines.org.uk/media/3647/conestat-alfa-ruconest-final-20180808-for-website.pdf Updates decision 21/08/18	16/10/2018
crizotinib 200mg, 250mg hard capsules (Xalkori®)	1329/18	Treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC).	Routinely available in line with national guidance, SMC 1329/18 https://www.scottishmedicines.org.uk/media/3465/crizotinib-xalkori-final-may-2018-for-website.pdf	19/06/2018
dabrafenib 50mg, 75mg hard capsules (Tafinlar®)	2131	In combination with trametinib for the adjuvant treatment of adults with Stage III melanoma with a BRAF V600 mutation, following complete resection.	Routinely available in line with national guidance, SMC 2131 https://www.scottishmedicines.org.uk/media/4124/dabrafenib-tafinlar-final-jan-2019-for-website.pdf	19/02/2019

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denosumab 120mg solution for injection (Xgeva®)	2110	Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with haematological malignancies involving bone.	Not routinely available as not recommended for use in NHS Scotland, SMC 2110 https://www.scottishmedicines.org.uk/media/3648/denosumab-xgeva-non-sub-final-july-2018-for-website.pdf	21/08/2018
denosumab 60mg solution for injection in pre-filled syringe (Prolia®)	2117	Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.	Not routinely available as not recommended for use in NHS Scotland, SMC 2117 https://www.scottishmedicines.org.uk/media/3688/denosumab-prolia-non-sub-final-august-2018-for-website.pdf	18/09/2018
dexmedetomidine 100micrograms/mL concentrate for solution for infusion (Dexdor®)	2161	Sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation.	Not routinely available as not recommended for use in NHS Scotland, SMC 2161 https://www.scottishmedicines.org.uk/media/4125/dexmedetomidine-dexdor-non-sub-final-jan-2019-for-website.pdf	19/02/2019
dimethyl fumarate 30mg, 120mg gastro-resistant tablets (Skilarence®)	1313/18	For the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy. **SMC restriction:** for use in patients in whom other non-biologic systemic treatments (methotrexate, ciclosporin and acitretin) are not appropriate or have failed and who are considered unsuitable for biologic therapy given their current disease state or personal preference.	Routinely available in line with national guidance, SMC 1313/18 https://www.scottishmedicines.org.uk/medicines-advice/dimethyl-fumarate-skilarence-fullsubmission/ Updates decision 17/04/18	21/08/2018

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dinutuximab beta 4.5mg/mL concentrate for solution for infusion (Qarziba®)	2105	For the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.	Routinely available in line with national guidance, SMC 2105 https://www.scottishmedicines.org.uk/media/3851/dinutuximab-beta-quarziba-final-oct-2018.pdf Updates decision 20/11/18	15/01/2019
dupilumab 300mg solution for injection in pre-filled syringe (Dupixent®)	2011	The treatment of moderate-to-severe atopic dermatitis in adult patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.	Routinely available in line with national guidance, SMC 2011 https://www.scottishmedicines.org.uk/media/3751/dupilumab-dupixent-final-august-2018-for-website.pdf Updates decision 18/09/18	20/11/2018
Epclusa® 400mg/100mg film-coated tablets (sofosbuvir/velpatasvir)	1271/17	Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** in patients with genotype 1 or 4 HCV infection.	Routinely available in line with national guidance, SMC 1271/17 https://www.scottishmedicines.org.uk/media/3272/sofosbuvir-velpatasvir-epclusa-resubmission-final-march-2018-for-website.pdf Updates decision 17/04/18	19/06/2018
epoetin alfa 2,000, 4,000, 10,000, 40,000 international units per mL solution for injection in pre-filled syringe (Eprex®)	2164	For the treatment of symptomatic anaemia (haemoglobin concentration of ≤10g/dL) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (<200 mU/mL).	Not routinely available as not recommended for use in NHS Scotland, SMC 2164 https://www.scottishmedicines.org.uk/media/4221/epoetin-alfa-eprex-non-sub-final-feb-2019-for-website.pdf	19/03/2019

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ertugliflozin L-pyroglutamic acid 5mg, 15mg film-coated tablets (Steglatro®)	2102	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: - As monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. - In addition to other medicinal products for the treatment of diabetes. **SMC restriction:** for use as monotherapy and as add-on therapy. When used as monotherapy it is restricted to patients who would otherwise receive a dipeptidyl peptidase-4 inhibitor and in whom a sulphonylurea or pioglitazone is not appropriate.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/01/2019
eslicarbazepine acetate 200mg, 800mg tablets (Zebinix®)	2090	As monotherapy in the treatment of partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2090 https://www.scottishmedicines.org.uk/media/3466/eslicarbazepine-acetate-zebinix-non-sub-for-website.pdf	19/06/2018
eslicarbazepine acetate 200mg, 800mg tablets, 50mg/mL oral suspension (Zebinix®)	2087	As adjunctive therapy in adolescents and children aged 6 years to <18 years with partial-onset seizures with or without secondary generalisation. **SMC restriction:** patients with highly refractory epilepsy who have been heavily pre-treated and remain uncontrolled with existing anti-epileptic drugs.	Routinely available in line with national guidance, SMC 2087 https://www.scottishmedicines.org.uk/media/4128/eslicarbazepine-zebinix-abbreviated-final-august-2018-revised-100119-for-website.pdf	19/02/2019
everolimus 2mg, 3mg, 5mg dispersible tablets (Votubia®)	1331/18	As adjunctive treatment of patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC).	Routinely available in line with national guidance, SMC 1331/18 https://www.scottishmedicines.org.uk/media/3467/everolimus-votubia-final-may-2018-for-website.pdf Updates decision 19/06/18	19/02/2019

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evolocumab 140mg solution for injection in pre-filled syringe, pre-filled pen, 420mg solution of injection in cartridge (Repatha SureClick®)	2133	In adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: - in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or, - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.	Not routinely available as not recommended for use in NHS Scotland, SMC 2133 https://www.scottishmedicines.org.uk/media/3852/evolocumab-repatha-non-sub-oct-2018.pdf	20/11/2018
flutiform k-haler® 50microgram/5microgram, 125microgram/5microgram pressurised inhalation suspension (fluticasone propionate/formoterol fumarate)	2016	For the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA)] is appropriate: - for patients not adequately controlled with ICS as 'as required' inhaled short-acting beta2-agonist or - for patients already adequately controlled on both ICS and a LABA.	This medicine is now withdrawn from use/discontinued, Updates decision 19/06/18	20/04/2021
fosaprepitant dimeglumine 150mg powder for solution for infusion (IVEMEND)®	2108	Prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in paediatric patients aged 6 months to <18 years. Fosaprepitant is given as part of a combination therapy.	Routinely available in line with national guidance, SMC 2108 https://www.scottishmedicines.org.uk/media/3854/fosaprepitant-ivemend-abb-final-oct-2018.pdf Updates decision 20/11/18	18/12/2018
gemtuzumab ozogamicin 5mg powder for concentrate for solution for infusion (Mylotarg®)	2089	For combination therapy with daunorubicin and cytarabine for the treatment of patients aged 15 years and older with previously untreated, de novo CD33 positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL). **SMC restriction:** use in patients with a favourable, intermediate or unknown cytogenetic profile.	Routinely available in line with national guidance, SMC 2089 https://www.scottishmedicines.org.uk/media/3765/gemtuzumab-ozogamicin-mylotarg-final-september-2018-for-website.pdf Updates decision 16/10/18	17/03/2020

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glycerol phenylbutyrate 1.1g/mL oral liquid (Ravicti®)	1342/18	Adjunctive therapy for chronic management of adult and paediatric patients ≥ 2 months of age with urea cycle disorders (UCDs) including deficiencies of carbamoyl phosphate synthase I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Glycerol phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, protein-free calorie supplements).	Routinely available in line with national guidance, SMC 1342/18 https://www.scottishmedicines.org.uk/media/3649/glycerol-phenylbutyrate-ravict-final-july-2018-for-website.pdf Updates decision 21/08/18	16/10/2018
guselkumab 100mg solution for injection (Tremfya®)	1340/18	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** for patients who have failed to respond to conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments.	Routinely available in line with national guidance, SMC 1340/18 https://www.scottishmedicines.org.uk/media/3473/guselkumab-tremfya-final-may-2018-amended-060618-for-website.pdf Updates decision 19/06/18	21/08/2018
Harvoni® 90mg/400mg film-coated tablets (ledipasvir/sofosbuvir)	1343/18	Treatment of chronic hepatitis C virus (HCV) infection in adolescents aged 12 to <18 years. **SMC restriction:** in patients with genotype 1 or 4 HCV infection.	Routinely available in line with national guidance, SMC 1343/18 https://www.scottishmedicines.org.uk/media/3470/ledispavir-sofosbuvir-harvoni-abb-final-may-2018-for-website.pdf	19/06/2018

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hydrocortisone 0.5mg, 1mg, 2mg, 5mg granules in capsules for opening (Alkindi®)	2088	Replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <18 years old). **SMC restriction**: for the first-line treatment of infants and young children with adrenal insufficiency aged from birth to less than six years of age for whom hydrocortisone must otherwise be individually prepared by manipulation such as by compounding (or crushing) or by production of special solutions in order to produce age-appropriate doses, or hydrocortisone given as off-label buccal tablets.	Routinely available in line with national guidance, SMC 2088 https://www.scottishmedicines.org.uk/media/3758/hydrocortisone-granules-alkindi-final-september-2018-for-website.pdf Updates decision 16/10/18	15/01/2019
icatibant acetate 30mg solution for injection in pre-filled syringe (Firazyr®)	1332/18	Symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency.	Routinely available in line with national guidance, SMC 1332/18 https://www.scottishmedicines.org.uk/media/3405/icatibant-acetate-firazyr-abbreviated-final-april-2018-for-website.pdf	15/05/2018
inotuzumab ozogamicin 1mg powder for concentrate for solution for infusion (BESPONSA®)	1328/18	As monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive relapsed or refractory B cell precursor ALL should have failed treatment with at least one tyrosine kinase inhibitor. **SMC restriction:** in patients for whom the intent is to proceed to stem cell transplantation.	Routinely available in line with national guidance, SMC 1328/18 https://www.scottishmedicines.org.uk/media/3469/inotuzumab-ozogamicin-besponsa-final-may-2018-for-website.pdf Updates decision 19/06/18	18/09/2018
ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®)	2094	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adolescents 12 years of age and older.	Routinely available in line with national guidance, SMC 2094 https://www.scottishmedicines.org.uk/media/3767/ipilimumab-yervoy-abb-final-sept-2018-for-website.pdf	16/10/2018

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ixazomib 2.3mg, 3mg, 4mg hard capsules (Ninlaro®)	2099	In combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2099 https://www.scottishmedicines.org.uk/media/3556/ixazomib-ninlaro-non-sub-final-june-2018-for-website.pdf	17/07/2018
ixekizumab 80mg solution for injection in pre-filled syringe or pen (Taltz®)	2097	Alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. **SMC restriction:** patients whose disease has not responded adequately to at least two conventional DMARDs given either alone or in combination, and who have had an inadequate response to a tumour necrosis factor (TNF)-inhibitor.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	16/10/2018
Juluca® 50mg/25mg film-coated tablets (dolutegravir/rilvipirine)	2091	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase inhibitor.	Routinely available in line with national guidance, SMC 2091 https://www.scottishmedicines.org.uk/media/3689/dolutegravir-rilpivirine-juluca-final-august-2018-amended-310818-for-website.pdf Updates decision 18/09/18	20/11/2018
letermovir 240mg film-coated tablets (Prevymis®)	1338/18	For the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT). Consideration should be given to official guidance on the appropriate use of antiviral agents.	Routinely available in line with national guidance, SMC 1338/18 https://www.scottishmedicines.org.uk/media/4222/letermovir-prevymis-final-june-2018-amended-30119-for-website.pdf Updates decision 19/03/19	21/05/2019

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liposomal formulation of daunorubicin/cytarabine 44mg/100mg powder for concentrate for solution for infusion (Vyxeos®)	2130	For the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).	Routinely available in line with national guidance, SMC 2130 https://www.scottishmedicines.org.uk/media/4223/liposomal-formulation-of-daunorubicin-cytarabine-vyxeos-final-feb-2019-for-website.pdf Updates decision 19/03/19	21/05/2019
lutetium (^{177}Lu) oxodotreotide 370MBq/mL solution for infusion (Lutathera®)	1337/18	Treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults.	Routinely available from a specialist centre in another health board, SMC 1337/18 https://www.scottishmedicines.org.uk/media/3557/lutetium-177lu-oxodotreotide-lutathera-final-june-2018-for-website.pdf Updates decision 17/07/18	18/12/2018
midostaurin 25mg soft capsules (Rydapt®)	2100	As monotherapy for the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm, or mast cell leukaemia.	Not routinely available as not recommended for use in NHS Scotland, SMC 2100 https://www.scottishmedicines.org.uk/media/3558/midostaurin-rydapt-non-sub-final-june-2018-for-website.pdf	17/07/2018
midostaurin 25mg soft capsules (Rydapt®)	1330/18	In combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FMS like tyrosine kinase 3 (FLT3) mutation-positive.	Routinely available in line with national guidance, SMC 1330/18 https://www.scottishmedicines.org.uk/media/3471/midostaurin-rydapt-final-may-2018-for-website.pdf Updates decision 19/06/18	15/06/2021

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Mysimba® 8mg/90mg prolonged-release tablets (naltrexone hydrochloride/bupropion hydrochloride)	2086	As an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index (BMI) of: 1) ≥30 kg/m^2 (obese), or 2) ≥27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension).	Not routinely available as not recommended for use in NHS Scotland, SMC 2086 https://www.scottishmedicines.org.uk/media/3406/naltrexone-bupropion-mysimba-non-sub-final-april-2018-for-website.pdf	15/05/2018
niraparib tosylate monohydrate 100mg hard capsules (Zejula®)	1341/18	As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. **SMC restriction:** to patients who do not have a germline BRCA mutation.	Routinely available in line with national guidance, SMC 1341/18 https://www.scottishmedicines.org.uk/media/3650/niraparib-tosylate-monohydrate-zejula-final-july-2018-amended-240718-for-website.pdf Updates decision 21/08/18	16/10/2018
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	2112	As monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.	Routinely available in line with national guidance, SMC 2112 https://www.scottishmedicines.org.uk/media/3958/nivolumab-opdivo-final-nov-2018-for-website.pdf Updates decision 18/12/18	19/02/2019
nusinersen 12mg solution for injection (Spinraza®)	1318/18	For the treatment of 5q spinal muscular atrophy (SMA). **SMC restriction:** patients with symptomatic type 1 SMA (infantile onset).	Not routinely available in NHS Grampian. If local need identified treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme. Updates decision 15/05/18	21/07/2020
obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®)	2015	In combination with chemotherapy, followed by obinutuzumab maintenance therapy in patients achieving a response, for the treatment of patients with previously untreated advanced follicular lymphoma.	Not routinely available as not recommended for use in NHS Scotland, SMC 2015 https://www.scottishmedicines.org.uk/media/3691/obinutuzumab-gazyvaro-resubmission-final-august-2018-for-website.pdf	18/09/2018

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ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®)	2121	For the treatment relapsing remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features. **SMC restriction:** who are contra-indicated or otherwise unsuitable for alemtuzumab.	Routinely available in line with national guidance, SMC 2121 https://www.scottishmedicines.org.uk/medicines-advice/ocrelizumab-ocrevus-resubmission-smc2121/ Updates decision 18/12/18	19/02/2019
parathyroid hormone 25micrograms/dose, 50micrograms/dose, 75micrograms/dose, 100micrograms/dose powder and solvent for solution for injection (Natpar®)	1334/18	As adjunctive treatment of adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone.	This medicine is now withdrawn from use/discontinued, Updates decision 17/04/18	20/12/2022
pembrolizumab 25mg/mL concentrate for solution for infusion, 50mg powder for concentrate for solution for infusion (Keytruda®)	2143	As monotherapy for the treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a ≥50% TPS and progressing on or after platinum-containing chemotherapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2143 https://www.scottishmedicines.org.uk/media/3959/pembrolizumab-keytruda-non-sub-final-nov-2018-for-website.pdf	18/12/2018
pembrolizumab 25mg/mL concentrate for solution for infusion, 50mg powder for concentrate for solution for infusion (Keytruda®)	1339/18	As monotherapy, for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS)≥10.	Not routinely available as not recommended for use in NHS Scotland, SMC 1339/18 https://www.scottishmedicines.org.uk/media/3692/pembrolizumab-keytruda-final-august-2018-for-website.pdf	18/09/2018
pertuzumab 420mg concentrate for solution for infusion (Perjeta®)	2119	In combination with trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.	Routinely available in line with national guidance, SMC 2119 https://www.scottishmedicines.org.uk/media/3960/pertuzumab-perjeta-resub-final-nov-2018-for-website.pdf Updates decision 18/12/18	18/06/2019

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
pertuzumab 420mg concentrate for solution for infusion (Perjeta®)	2120	In combination with trastuzumab and docetaxel, in adult patients with HER2 positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti HER2 therapy or chemotherapy for their metastatic disease.	Routinely available in line with national guidance, SMC 2120 https://www.scottishmedicines.org.uk/media/4008/pertuzumab-perjeta-resubmission-final-dec-2018-for-website.pdf Updates decision 15/01/19	19/03/2019
progesterone 25mg solution for injection (Lubion®)	2017	In adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	17/07/2018
raltegravir 100mg granules for oral suspension (Isentress®)	2101	In combination with other anti-retroviral medicinal products in the treatment of human immunodeficiency virus in neonates.	Not routinely available as not recommended for use in NHS Scotland, SMC 2101 https://www.scottishmedicines.org.uk/media/3561/raltegravir-isentress-non-sub-final-june-2018-for-website.pdf	17/07/2018
regorafenib 40mg film-coated tablets (Stivarga®)	1316/18	As monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib.	Routinely available in line with national guidance, SMC 1316/18 https://www.scottishmedicines.org.uk/media/3408/regorafenib-stivarga-final-april-2018-for-website.pdf Updates decision 15/05/18	19/06/2018
rituxumab 100mg, 500mg solution for infusion (MabThera®)	2165	In combination with glucocorticoids, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA).	Not routinely available as not recommended for use in NHS Scotland, SMC 2165 https://www.scottishmedicines.org.uk/media/4224/rituxumab-mabthera-non-sub-final-feb-2019-for-website.pdf	19/03/2019

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
rivaroxaban 2.5mg film-coated tablets (Xarelto®)	2128	Co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with: - coronary artery disease, or - symptomatic peripheral artery disease at high risk of ischaemic events. **SMC restriction:** use in patients with stable coronary artery disease that does not require dual antiplatelet therapy.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. Updates decision 19/02/19	18/02/2020
romiplostim 125micrograms powder for solution for injection, vial (Nplate®)	2126	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 to <18 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). **SMC restriction:** to use in patients with severe symptomatic ITP or patients with a high risk of bleeding.	Routinely available in line with national guidance, SMC 2126 https://www.scottishmedicines.org.uk/media/4131/romiplostim-nplate-abb-final-jan-2019-for-website.pdf	19/02/2019
sapropterin dihydrochloride 100mg soluble tablets (Kuvan®)	558/09	Treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment.	Not routinely available as not recommended for use in NHS Scotland, ADVICE ARCHIVED, replaced by FG advice published 29/12/2023 (FG meeting 19/12/2023).	21/08/2018

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
sarilumab 150mg, 200mg solution for injection in pre-filled syringe, pre-filled pen (Kevzara®)	1314/18	In combination with methotrexate for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Sarilumab can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate. **SMC restriction:** in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a TNF antagonist, it may be used in patients ineligible to receive rituximab.	Routinely available in line with national guidance, SMC 1314/18 https://www.scottishmedicines.org.uk/media/3270/sarilumab-kevzara-final-march-2018-for-website.pdf Updates decision 17/04/18	16/10/2018
selexipag 200microgram, 400microgram, 600microgram, 800microgram, 1,000microgram, 1,200microgram, 1,400microgram, 1,600microgram film-coated tablets (Uptravi®)	1235/17	For the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class III, as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and a phosphodiesterase type 5 (PDE-5) inhibitor and who would be considered for treatment with inhaled iloprost.	Routinely available from a specialist centre in another health board. If local need identified treatment is initiated and prescribed by specialists in the Scottish Pulmonary Vascular Unit.	15/05/2018

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
semaglutide 0.25mg, 0.5mg, 1mg solution for injection in pre-filled pen (Ozempic®)	2092	The treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise: - As monotherapy when metformin is considered inappropriate due to intolerance or contraindications - In addition to other medicinal products for the treatment of diabetes. **SMC restriction:** in addition to other oral anti-diabetic medicines, or as an add-on to basal insulin, as an alternative glucagon-like peptide-1 receptor agonist option.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/01/2019
sirolimus 0.5mg, 1mg, 2mg coated tablets, 1mg/mL oral solution (Rapamune®)	2173	Treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function.	Not routinely available as not recommended for use in NHS Scotland, SMC 2173 https://www.scottishmedicines.org.uk/media/3759/sirolimus-rapamune-non-sub-final-sept-2018-for-website.pdf	16/10/2018
teduglutide 5mg, 1.25mg vials of powder and solvent for solution for injection (Revestive®)	1139/16	For the treatment of patients aged one year and above with short bowel syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery. **SMC restriction**: initiation in paediatric patients (aged 1 to <18 years).	Routinely available in line with national guidance, SMC 1139/16 https://www.scottishmedicines.org.uk/media/3273/teduglutide-revestive-final-jan-2018-revised-060318-for-website.pdf Updates decision 17/04/18	15/05/2018
telotristat ethyl 250mg film-coated tablets (Xermelo®)	1327/18	Treatment of carcinoid syndrome diarrhoea in combination with somatostatin analogue therapy in adults inadequately controlled by somatostatin analogue therapy. **SMC restriction:** patients with carcinoid syndrome diarrhoea who experience an average of four or more bowel motions per day, despite receiving somatostatin analogue therapy.	Routinely available in line with national guidance, SMC 1327/18 https://www.scottishmedicines.org.uk/media/3472/telotristat-ethyl-xermelo-final-may-2018-for-website.pdf Updates decision 19/06/18	17/07/2018

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
tiotropium 2.5microgram solution for inhalation (Spiriva Respimat®)	2118	As add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/01/2019
tisagenlecleucel 1.2 x 10^6 - 6 x 10^8 cells dispersion for infusion (Kymriah®)	2129	Treatment of paediatric and young adults up to 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse.	Routinely available from a specialist centre in another health board, SMC 2129 https://www.scottishmedicines.org.uk/media/4132/tisagenlecleucel-kymriah-final-jan-2019-for-website.pdf	19/02/2019
tivozanib 890micrograms, 1,340micrograms hard capsules (Fotivda®)	1335/18	For the first-line treatment of adults with advanced renal cell carcinoma (RCC).	Routinely available in line with national guidance, SMC 1335/18 https://www.scottishmedicines.org.uk/media/3562/tivozanib-fotivda-final-june-2018-for-website.pdf Updates decision 17/07/18	19/02/2019
tocilizumab 162mg solution for injection in pre-filled syringe, pre-filled pen (RoActemra®)	2014	Treatment of Giant Cell Arteritis (GCA) in adult patients **SMC restriction:** treatment with tocilizumab is subject to a 12 months clinical stopping rule.	Routinely available in line with national guidance, SMC 2014 https://www.scottishmedicines.org.uk/media/3693/tocilizumab-roactemra-final-august-2018-for-website.pdf Updates decision 18/09/18	16/04/2019
tofacitinib citrate 5mg film-coated tablets (Xeljanz®)	2116	In combination with methotrexate for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **SMC restriction:** for use in patients with psoriatic arthritis whose disease has not responded adequately to at least two conventional DMARDs, given either alone or in combination.	Routinely available in line with national guidance, SMC 2116 https://www.scottishmedicines.org.uk/media/4011/tofacitinib-xeljanz-final-dec-2018-amended-070119-for-website.pdf Updates decision 15/01/19	16/04/2019
tofacitinib citrate 5mg, 10mg film-coated tablets (Xeljanz®)	2122	For the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.	Not routinely available as there is a local preference for alternative medicines Updates decision 19/02/19	16/05/2023

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Vosevi® 400mg/100mg/100mg film-coated tablets (sofosbuvir/velpatasvir/voxilaprevir)	1317/18	Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction**: for patients who: - have failed to achieve a sustained virologic response (SVR) with a direct-acting anti-viral (DAA), or - are DAA-naïve, have genotype 3 (GT3) HCV infection, with or without cirrhosis, and are suitable for treatment with an eight-week course.	Routinely available in line with national guidance, SMC 1317/18 https://www.scottishmedicines.org.uk/media/3271/sofosbuvir-velpatasvir-voxilaprevir-vosevi-final-march-2018-amended-030418-for-website.pdf Updates decision 17/04/18	19/06/2018