NHS Grampian
Formulary Group Decisions for SMC advice published April 2020 to March 2021

This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) advice published April 2020 to March 2021.

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

December 2022

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
afamelanotide 16mg implant (Scenesse®)	1251/17	Prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).	Not routinely available as not recommended for use in NHS Scotland. If local need identified, treatment is available through the National Services Scotland Ultra-orphan medicines Risk Share Scheme.	16/02/2021
alpelisib 50mg, 100mg, 200mg film-coated tablets (Piqray®)	2339	In combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine therapy as monotherapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2339 https://www.scottishmedicines.org.uk/media/5759/alpelisib-piqray-non-sub-final-jan-2021-for-website.pdf	16/02/2021
andexanet alfa 200mg powder for solution for infusion (Ondexxya®)	2273	For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.	Routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment, SMC 2273 https://www.scottishmedicines.org.uk/media/5372/andexanet-alfa-ondexxya-final-august-2020-amended-180820-for-website.pdf Updates decision 15/09/20	20/10/2020
apremilast 10mg, 20mg, 30mg film-coated tablets (Otezla®)	2340	Treatment of adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2340 https://www.scottishmedicines.org.uk/media/5760/apremilast-otezla-non-sub-final-jan-2021-for-website.pdf	16/02/2021
atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®)	2279	Atezolizumab, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).	Routinely available in line with national guidance, SMC 2279 https://www.scottishmedicines.org.uk/media/5559/atezolizumab-tecentriq-es-sclc-final-october-2020-for-website.pdf Updates decision 17/11/20	20/04/2021

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atezolizumab 840mg concentrate for solution for infusion (Tecentriq®)	2267	Atezolizumab in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death-ligand 1 [PD-L1] expression ≥1% and who have not received prior chemotherapy for metastatic disease.	Routinely available in line with national guidance, SMC 2267 https://www.scottishmedicines.org.uk/media/5560/atezolizumab-tecentriq-tnbc-final-october-2020-amended-161020-for-website.pdf Updates decision 17/11/20	17/08/2021
avatrombopag 20mg film-coated tablets (Doptelet®)	2296	Treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.	Routinely available in line with national guidance, SMC 2296 https://www.scottishmedicines.org.uk/media/5651/avatrombopag-doptelet-final-october-2020-for-website.pdf Updates decision 15/12/20	16/03/2021
avelumab 20mg/mL concentrate for solution for infusion (Bavencio®)	2248	In combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/10/2020
brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®)	2310	In combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL).	Routinely available in line with national guidance, SMC 2310 https://www.scottishmedicines.org.uk/media/5705/brentuximab-vedotin-adcetris-final-december-2020docx-for-website.pdf Updates decision 19/01/21	18/05/2021
brigatinib 30mg, 90mg, 180mg film-coated tablets (Alunbrig®)	2314	As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.	Not routinely available as there is a local preference for alternative medicines, Updates decision 19/01/21	21/06/2022
brolucizumab 120mg/mL solution for injection in prefilled syringe (Beovu®)	2272	In adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).	Not routinely available as there is a local preference for alternative medicines, Updates decision 15/09/20	20/12/2022

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budesonide 1mg orodispersible tablets (Jorveza®)	2158	Treatment of eosinophilic oesophagitis (EoE) in adults (older than 18 years of age). **SMC restriction:** for patients unsuccessfully treated with proton pump inhibitors.	Routinely available in line with local guidance Updates decision 20/10/20	16/02/2021
cannabidiol 100mg/mL oral solution (Epidyolex®)	2262	For use as adjunctive therapy of seizures associated with Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older.	Routinely available in line with national guidance, SMC 2262 https://www.scottishmedicines.org.uk/media/5365/cannabidiol-epidyolex-ds-final-august-2020docx-for-website.pdf Updates decision 15/09/20	15/12/2020
cannabidiol 100mg/mL oral solution (Epidyolex®)	2263	For use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older.	Routinely available in line with national guidance, SMC 2263 https://www.scottishmedicines.org.uk/media/5366/cannabidiol-epidyolex-lgs-final-august-2020docx-for-website.pdf Updates decision 15/09/20	15/12/2020
caplacizumab 10mg powder and solvent for solution for injection (Cablivi®)	2266	Treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.	Routinely available in line with national guidance, SMC 2266 https://www.scottishmedicines.org.uk/media/5367/caplacizumab-cablivi-final-august-2020docx-for-website.pdf Updates decision 15/09/20	17/11/2020
carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®)	2290	In combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **SMC restriction:** for patients who have received only one prior therapy.	Routinely available in line with national guidance, SMC 2290 https://www.scottishmedicines.org.uk/media/5461/carfilzomib-kyprolis-resub-final-sept-2020-for-website.pdf Updates decision 20/10/20	16/02/2021
daratumumab 1,800mg solution for subcutaneous injection (Darzalex®)	2301	In combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only.	Routinely available in line with national guidance, SMC 2301 https://www.scottishmedicines.org.uk/media/5653/daratumumab-darzalex-mm-abb-final-september-2020-for-website.pdf	20/10/2020

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daratumumab 1,800mg solution for subcutaneous injection (Darzalex®)	2304	As monotherapy, as a fourth-line treatment option in adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.	Routinely available in line with national guidance, SMC 2304 https://www.scottishmedicines.org.uk/media/5654/daratumumab-darzalex-rrmm-abb-final-september-2020-for-website.pdf	20/10/2020
daratumumab 1,800mg solution for subcutaneous injection (Darzalex®)	2326	In combination with bortezomib, thalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.	Routinely available in line with national guidance, SMC 2326 https://www.scottishmedicines.org.uk/media/5718/daratumumab-darzalex-abb-final-december-2020docx-for-website.pdf Updates decision 19/01/21	15/06/2021
daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®)	2302	In combination with bortezomib, thalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.	Routinely available in line with national guidance, SMC 2302 https://www.scottishmedicines.org.uk/media/5707/daratumumab-darzalex-final-dec-2020docx-for-website.pdf Updates decision 19/01/21	15/06/2021
darolutamide 300mg film-coated tablets (Nubeqa®)	2297	For the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.	Routinely available in line with national guidance, SMC 2297 https://www.scottishmedicines.org.uk/media/5563/darolutamide-nubeqa-final-october-2020-for-website.pdf Updates decision 17/11/20	20/04/2021
Delstrigo® 100mg/300mg/245mg film-coated tablets (doravirine/lamivudine/tenofovir disoproxil fumarate)	2333	For the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.	Routinely available in line with national guidance, SMC 2333 https://www.scottishmedicines.org.uk/media/5816/doravirine-delstrigo-abbreviated-final-feb-2021-for-website.pdf Updates decision 16/03/21	20/04/2021

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doravirine 100mg film-coated tablets (Pifeltro®)	2332	In combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.	Routinely available in line with national guidance, SMC 2332 https://www.scottishmedicines.org.uk/media/5811/doravirine-pifeltro-abbreviated-final-feb-2021-for-website.pdf Updates decision 16/03/21	20/04/2021
dupilumab 300mg solution for injection in pre-filled pen, pre-filled syringe (Dupixent®)	2324	As an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyposis for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.	Not routinely available as not recommended for use in NHS Scotland, SMC 2324 https://www.scottishmedicines.org.uk/media/5708/dupilumab-dupixent-non-sub-final-dec-2020docx-for-website.pdf	19/01/2021
entrectinib 100mg, 200mg hard capsules (Rozlytrek®)	2294	As monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/01/2021
entrectinib 100mg, 200mg hard capsules (Rozlytrek®)	2295	As monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion: - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and - who have not received a prior NTRK inhibitor - who have no satisfactory treatment options	Not routinely available as local implementation plans are being developed, SMC 2295 https://www.scottishmedicines.org.uk/media/5812/entrectinib-rozlytrek-final-feb-2021docx-for-website.pdf Updates decision 16/03/21	16/11/2021
esketamine 28mg nasal spray solution (Spravato®)	2258	In combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.	Routinely available in line with national guidance, SMC 2258 https://www.scottishmedicines.org.uk/media/5353/esketamine-spravato-final-august-2020docx-for-website.pdf Updates decision 15/09/20	18/01/2022

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ex vivo expanded autologous human corneal epithelial cells containing stem cells (Holoclar®)	2261	Treatment of adult patients with moderate to severe limbal stem cell deficiency (defined by the presence of superficial corneal neovascularisation in at least two corneal quadrants, with central corneal involvement, and severely impaired visual acuity), unilateral or bilateral, due to physical or chemical ocular burns.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/09/2020
fampridine 10mg prolonged-release tablets (Fampyra®)	2253	For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).	Routinely available in line with national guidance, SMC 2253 https://www.scottishmedicines.org.uk/media/5165/fampridine-fampyra-final-march-2020-for-website.pdf Updates decision 21/04/20	21/06/2022
fluocinolone acetonide 190micrograms intravitreal implant (Iluvien®)	2260	Prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.	Routinely available in line with national guidance, SMC 2260 https://www.scottishmedicines.org.uk/media/5355/fluocinolone-acetonide-lluvien-final-august-2020docx-for-website.pdf Updates decision 15/09/20	18/05/2021
fostamatinib 100mg, 150mg film-coated tablets (Tavlesse®)	2300	Treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. **SMC restriction**: for the treatment of patients with severe symptomatic ITP or with a high risk of bleeding who have not had a suitable response to other therapies, including a thrombopoietin receptor-agonist (TPO-RA), or where use of a TPO-RA is not appropriate.	Routinely available in line with national guidance, SMC 2300 https://www.scottishmedicines.org.uk/media/5710/fostamatinib-tavlesse-final-dec-2020docx-for-website.pdf Updates decision 19/01/21	20/04/2021
gilteritinib 40mg film-coated tablets (Xospata®)	2252	As monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation.	Routinely available in line with national guidance, SMC 2252 https://www.scottishmedicines.org.uk/media/5356/gilteritinib-xospata-final-august-2020docx-for-website.pdf Updates decision 15/09/20	19/01/2021

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glasdegib 25mg, 100mg film-coated tablets (Daurismo®)	2341	In combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukaemia (AML) in adult patients who are not candidates for standard induction chemotherapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2341 https://www.scottishmedicines.org.uk/media/5763/glasdegib-daurismo-non-sub-final-jan-2021-for-website.pdf	16/02/2021
hydroxycarbamide 100mg/mL oral solution (Xromi®)	2271	For the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 2 years of age. **SMC restriction:** children who are too young to be able to swallow capsules / tablets and adults and adolescents who have difficulty in swallowing solid oral dosage forms.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	18/08/2020
ibrutinib 140mg, 280mg, 420mg film-coated tablets (Imbruvica®)	2259	In combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia. **SMC restriction:** for use in patients who have received at least one prior therapy.	Routinely available in line with national guidance, SMC 2259 https://www.scottishmedicines.org.uk/media/5464/ibrutinib-imbruvica-final-september-2020-for-website.pdf Updates decision 20/10/20	19/01/2021
lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg hard capsules (Revlimid®)	2281	In combination with rituximab (anti-CD20 antibody) for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 to 3a).	Routinely available in line with national guidance, SMC 2281 https://www.scottishmedicines.org.uk/media/5465/lenalidomide-revlimid-fl-final-september-2020-for-website.pdf Updates decision 20/10/20	19/01/2021
lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg hard capsules (Revlimid®)	2289	As monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT).	Routinely available in line with national guidance, SMC 2289 https://www.scottishmedicines.org.uk/media/5466/lenalidomide-revlimid-mm-final-september-2020-for-website.pdf Updates decision 20/10/20	16/02/2021

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leuprorelin acetate 3.75mg, 11.25mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe (Prostap® SR DCS, Prostap® 3 DCS)	2319	As adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence (young age, high grade tumour, lymph node involvement). In women who have received chemotherapy, premenopausal status must be confirmed after completion of chemotherapy.	Routinely available in line with national guidance, SMC 2319 https://www.scottishmedicines.org.uk/media/5752/leuprorelin-acetate-prostap-dcs-ebc-abb-final-jan-2021-for-website.pdf Updates decision 16/02/21	19/10/2021
leuprorelin acetate 3.75mg, 11.25mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe (Prostap® SR DCS, Prostap® 3 DCS)	2320	As treatment in pre- and perimenopausal women with advanced breast cancer suitable for hormonal manipulation.	Routinely available in line with national guidance, SMC 2320 https://www.scottishmedicines.org.uk/media/5751/leuprorelin-acetate-prostap-dcs-abc-abb-final-jan-2021-for-website.pdf Updates decision 16/02/21	19/10/2021
melatonin 1mg, 5mg prolonged-release tablets (Slenyto®)	2306	Treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.	Not routinely available as not recommended for use in NHS Scotland, SMC 2306 https://www.scottishmedicines.org.uk/media/5711/melatonin-slenyto-resub-final-dec-2020docx-for-website.pdf	19/01/2021
mercaptamine 3.8mg/mL eye drops solution (Cystadrops®)	2343	Treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis.	Not routinely available as not recommended for use in NHS Scotland, SMC 2343 https://www.scottishmedicines.org.uk/media/5753/mercaptamine-cystadrops-non-sub-final-jan-2021-for-website.pdf	16/02/2021
mexiletine 167mg hard capsules (Namuscla®)	2307	For the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders.	Routinely available in line with national guidance, SMC 2307 https://www.scottishmedicines.org.uk/media/5655/mexiletine-namuscla-resub-final-nov-2020-for-website.pdf Updates decision 15/12/20	16/08/2022

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naldemedine 200micrograms film-coated tablets (Rizmoic®)	2242	For the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.	Routinely available in line with local guidance, ADVICE ARCHIVED, replaced by FG advice published 04/07/2022 (FG meeting 21/06/2022). Updates decision 21/04/20	15/06/2021
neratinib 40mg film-coated tablets (Nerlynx®)	2251	For the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.	Routinely available in line with national guidance, SMC 2251 https://www.scottishmedicines.org.uk/media/5275/neratinib-nerlynx-final-july-2020-for-website.pdf Updates decision 18/08/20	20/10/2020
omalizumab 75mg, 150mg solution for injection in pre-filled syringe (Xolair®)	2344	As add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control.	Not routinely available as not recommended for use in NHS Scotland, SMC 2344 https://www.scottishmedicines.org.uk/media/5754/omalizumab-xolair-non-sub-final-jan-2021-for-website.pdf	16/02/2021
onasemnogene abeparvovec 2 x 10^{13} vector genomes/mL solution for infusion (Zolgensma®)	2311	For the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene. **SMC restriction**: for the treatment of: - patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or - pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene, where patients are expected to develop SMA type 1	Routinely available from a specialist centre in another health board	16/03/2021

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ozanimod 0.23mg, 0.46mg, 0.92mg hard capsules (Zeposia®)	2309	Treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features. **SMC restriction:** suitable for or requesting an oral treatment.	Routinely available in line with national guidance, SMC 2309 https://www.scottishmedicines.org.uk/media/5755/ozanimod-zeposia-final-jan-2021-amended-2221-for-website.pdf Updates decision 16/02/21	18/05/2021
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	2247	In combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2247 https://www.scottishmedicines.org.uk/media/5357/pembrolizumab-keytruda-final-august-2020-amended-270820-for-website.pdf Updates decision 15/09/20	16/03/2021
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	2257	As monotherapy or in combination with platinum and fluorouracil chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express programmed cell death ligand-1 (PD-L1) with a combined positive score (CPS)≥1. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2257 https://www.scottishmedicines.org.uk/media/5369/pembrolizumab-keytruda-hnscc-final-august-2020docx-for-website.pdf Updates decision 15/09/20	19/01/2021
pertuzumab 420mg concentrate for solution for infusion (Perjeta®)	2284	For use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence. **SMC restriction:** for use in patients with lymph node-positive disease.	Routinely available in line with national guidance, SMC 2284 https://www.scottishmedicines.org.uk/media/5359/pertuzumab-perjeta-resub-final-august-2020docx-for-website.pdf Updates decision 15/09/20	21/12/2021

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polatuzumab vedotin 30mg, 140mg powder for concentrate for solution for infusion (Polivy®)	2282	In combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant.	Routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment, SMC 2282 https://www.scottishmedicines.org.uk/media/5360/polatuzumab-vedotin-polivy-final-august-2020-amended-180820-for-website.pdf Updates decision 15/09/20	15/12/2020
ravulizumab 300mg/30mL concentrate for solution for infusion (Ultomiris®)	2305	For the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH): - In patients with haemolysis with clinical symptom(s) indicative of high disease activity - In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months **SMC restriction:** under the advice of the national PNH service.	Routinely available in line with national guidance, SMC 2305 https://www.scottishmedicines.org.uk/media/5756/ravulizumab-ultomiris-final-jan-2021-for-website.pdf	16/02/2021
Recarbrio® 500mg/500mg/250mg powder for solution for infusion (imipenem/cilastatin/relabactam)	2342	For the treatment of: - hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults - bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults	Not routinely available as not recommended for use in NHS Scotland, SMC 2342 https://www.scottishmedicines.org.uk/media/5750/imipenem-cilastatin-relabactam-recarbrio-non-sub-final-jan-2021-for-website.pdf	16/02/2021
romosozumab 105mg solution for injection in prefilled pen (Evenity®)	2280	Treatment of severe osteoporosis in postmenopausal women at high risk of fracture. **SMC restriction:** to use in patients who have experienced a fragility fracture and are at imminent risk of another fragility fracture (within 24 months).	Routinely available in line with national guidance, SIGN 142 - Management of osteoporosis and the prevention of fragility fractures Updates decision 17/11/20	16/03/2021

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secukinumab 150mg solution for injection in pre-filled syringe, pre-filled pen (Cosentyx®)	2308	Treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non steroidal anti inflammatory drugs.	Routinely available in line with national guidance, SMC 2308 https://www.scottishmedicines.org.uk/media/5712/secukinumab-cosentyx-final-december-2020docx-for-website.pdf Updates decision 19/01/21	15/06/2021
semaglutide 3mg, 7mg, 14mg tablets (Rybelsus®)	2287	For the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise: - as monotherapy when metformin is considered inappropriate due to intolerance or contraindications - in combination with other medicinal products for the treatment of diabetes **SMC restriction: i**n 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	15/09/2020
siponimod 250microgram, 2mg film-coated tablets (Mayzent®)	2265	Treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity.	Routinely available in line with national guidance, SMC 2265 https://www.scottishmedicines.org.uk/media/5468/siponimod-mayzent-final-september-2020-for-website.pdf Updates decision 20/10/20	16/03/2021
sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®)	2288	Treatment of hyperkalaemia in adult patients. **SMC restriction:** patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia).	Routinely available in line with local guidance Updates decision 15/09/20	16/02/2021

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Suboxone® 2mg/0.5mg, 8mg/2mg sublingual film (buprenorphine/naloxone)	2316	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction. **SMC restriction:** to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.	Routinely available in line with national guidance, SMC 2316 https://www.scottishmedicines.org.uk/media/5761/buprenorphine-naloxone-suboxone-abb-final-jan-2021-for-website.pdf Updates decision 16/02/21	21/09/2021
Suliqua® 100units/mL / 50microgram/mL, 100units/mL / 33micrograms/mL solution for subcutaneous injection in pre-filled pens (insulin glargine/lixisenatide)	2235	In combination with metformin for the treatment of adults with type 2 diabetes mellitus, to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose-lowering medicinal product or with basal insulin. **SMC restriction:** for use in patients who are uncontrolled on basal insulin (glycosylated haemoglobin [HbA1c] >7.5% [59mmoL/moL]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin analogues.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/04/2020

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
talazoparib 0.25mg, 1mg hard capsules (Talzenna®)	2325	As monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo) adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2325 https://www.scottishmedicines.org.uk/media/5713/talazoparib-talzenna-non-sub-final-dec-2020docx-for-website.pdf	19/01/2021
trabectedin 0.25mg, 1mg powder for concentrate for solution for infusion (Yondelis®)	2283	Treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.	Routinely available in line with national guidance, SMC 2283 https://www.scottishmedicines.org.uk/media/5572/trabectedin-yondelis-resub-final-october-2020-for-website.pdf Updates decision 17/11/20	21/09/2021
trametinib 0.5mg, 2mg film-coated tablets (Mekinist®)	2328	In combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. **SMC restriction**: after first line treatment.	Not routinely available as there is a local preference for alternative medicines, Updates decision 16/03/21	21/06/2022
trastuzumab emtansine 100mg, 160mg powder for concentrate for solution for infusion (Kadcyla®)	2298	As a single agent, for the adjuvant treatment of adult patients with human epidermal growth factor-2 (HER2) positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2 targeted therapy.	Routinely available in line with national guidance, SMC 2298 https://www.scottishmedicines.org.uk/media/5578/trastuzumab-emtansine-kadcyla-final-october-2020-for-website.pdf Updates decision 17/11/20	17/08/2021

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Trimbow® (beclometasone dipropionate/formoterol fumarate dehydrate/glycopyrronium)	2335	For the maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.	Routinely available in line with local guidance, Use is subject to inclusion in the Respiratory Managed Clinical Network (MCN) framework for inhaled medicines Updates decision 16/03/21	20/04/2021
Trixeo® Aerosphere 5micrograms / 7.2micrograms / 160micrograms (formoterol fumarate dihydrate / glycopyrronium / budesonide)	2321	Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. **SMC restriction:** in patients with severe COPD (forced expiratory volume in one second [FEV1] less than 50% predicted normal).	Not routinely available as there is a local preference for alternative medicines, Updates decision 16/02/21	19/10/2021
upadacitinib 15mg prolonged-release tablets (Rinvoq®)	2315	For the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Upadacitinib may be used as monotherapy or in combination with methotrexate. **SMC restriction:** in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF antagonist in whom rituximab is not appropriate.	Routinely available in line with national guidance, https://www.scottishmedicines.org.uk/media/7346/upadacitinib-rinvoq-final-jan-2021-for-website.pdf Updates decision 16/02/21	19/10/2021

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
ustekinumab 130mg concentrate for solution for infusion, 90mg solution for injection in pre-filled syringe, 45mg solution for injection (vials) (Stelara®)	2250	For the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.	Routinely available in line with national guidance, SMC 2250 https://www.scottishmedicines.org.uk/media/5168/ustekinumab-stelara-final-march-2020-amended-010420-for-website.pdf Updates decision 21/04/20	20/10/2020
Vaborem® 1g/1g powder for concentrate for solution for infusion (meropenem/vaborbactam)	2278	For the treatment of the following infections in adults: - Complicated urinary tract infection (cUTI), including pyelonephritis - Complicated intra-abdominal infection (cIAI) - Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Meropenem/vaborbactam is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options. **SMC restriction:** for adults with confirmed carbapenem-resistant Enterobacteriaceae (CRE), which is involved in the production of Klebsiella pneumoniae carbapenemase (KPC) associated with cUTI (including acute pyelonephritis [AP]), cIAI, HAP (including VAP) and bacteraemia that occurs in association with, or is suspected to be associated with any of the infections previously mentioned. Use should be on the advice of local microbiologists or specialists in infectious disease.	Routinely available in line with national guidance, SMC 2278 https://www.scottishmedicines.org.uk/media/5467/meropenem-vaborbactam-vaborem-final-september-2020-for-website.pdf Updates decision 20/10/20	20/07/2021

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
vedolizumab 108mg solution for injection in pre-filled syringe, pre-filled pen (Entyvio®)	2276	For the maintenance treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.	Routinely available in line with local guidance	18/08/2020
vedolizumab 108mg solution for injection in pre-filled syringe, pre-filled pen (Entyvio®)	2277	For the maintenance treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumour necrosis factor-alpha (TNFα) antagonist.	Routinely available in line with local guidance	18/08/2020
venetoclax 10mg, 50mg, 100mg film-coated tablets (Venclyxto®)	2293	In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). **SMC restriction:** for use in: (1) patients without del (17p)/TP53 mutation who are not fit to receive FCR (fludarabine, cyclophosphamide and rituximab) chemo-immunotherapy (2) patients with del (17p)/TP53 mutation.	Routinely available in line with national guidance, SMC 2293 https://www.scottishmedicines.org.uk/media/5650/venetoclax-venclyxto-final-nov-2020-for-website.pdf Updates decision 15/12/20	16/03/2021