

NHS Grampian Formulary Group Decisions for SMC advice published April 2023 to March 2024



This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) advice published April 2023 to March 2024.

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

April 2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Acarizax 12 SQ-HDM oral lyophilisates (Dermatophagoides pteronyssinus and Dermatophagoides farinae)	2613	<p>1) Adults (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with at least one of the following conditions:</p> <ul style="list-style-type: none"> - persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication - house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment <p>2) Adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.</p>	<p>Not routinely available as not recommended for use in NHS Scotland, SMC 2613</p> <p>https://www.scottishmedicines.org.uk/media/7752/dermatophagoides-acarizax-non-sub-final-july-2023-for-website.pdf</p>	15/08/2023
aflibercept 40mg/mL solution for injection in pre-filled syringe (Eylea®)	2612	<p>In preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 2+ or 3+) or AP-ROP (aggressive posterior ROP) disease.</p>	<p>Not routinely available as not recommended for use in NHS Scotland, SMC 2612</p> <p>https://www.scottishmedicines.org.uk/media/7755/aflibercept-eylea-non-sub-final-july-2023-for-website.pdf</p>	15/08/2023
amivantamab 50mg/mL concentrate for solution for infusion (Rybrevant®)	2638	<p>As monotherapy for treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy.</p>	<p>Not routinely available as not recommended for use in NHS Scotland, SMC 2638</p> <p>https://www.scottishmedicines.org.uk/media/7987/amivantamab-rybrevant-non-sub-final-nov-2023-for-website.pdf</p>	19/12/2023

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apalutamide 60mg film-coated tablets (Erleada®)	2579	In adults for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/08/2023
atogepant 10mg, 60mg tablets (Aquipta®)	2599	For the prophylaxis of migraine in adults who have at least 4 migraine days per month. SMC restriction: for patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.	Routinely available in line with local guidance Updates decision 17/10/23	21/11/2023
avacopan 10mg hard capsules (Tavneos®)	2578	In combination with a rituximab or cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).	Routinely available in line with national guidance, SMC 2578 https://www.scottishmedicines.org.uk/media/7938/avacopan-tavneos-final-oct-2023-for-website.pdf Updates decision 21/11/23	16/04/2024
avalglucosidase alfa 100mg powder for concentrate for solution for infusion (Nexviadyme®)	2546	Long-term enzyme replacement therapy for the treatment of patients with Pompe disease (acid α -glucosidase deficiency).	Routinely available in line with national guidance, SMC 2546 https://www.scottishmedicines.org.uk/media/7700/avalglucosidase-alfa-nexviadyme-abb-final-june-2023-for-website.pdf	15/08/2023
axicabtagene ciloleucel 0.4 – 2 x 10 ⁸ cells dispersion for infusion (Yescarta®)	2628	For the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2628 https://www.scottishmedicines.org.uk/media/8169/axicabtagene-ciloleucel-yescarta-final-amended-060324-for-website.pdf	19/03/2024
axicabtagene ciloleucel 0.4 – 2 x 10 ⁸ cells dispersion for infusion (Yescarta®)	2646	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2646 https://www.scottishmedicines.org.uk/media/8028/axicabtagene-ciloleucel-non-sub-final-dec-2023-for-website.pdf	16/01/2024

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azacitidine 200mg, 300mg film-coated tablets (Onureg®)	2533	Maintenance therapy in adults with acute myeloid leukaemia who achieved complete remission or complete remission with incomplete blood count recovery following induction therapy with or without consolidation treatment and who are not candidates for, including those who choose not to proceed to, haematopoietic stem cell transplantation.	Routinely available in line with national guidance, SMC 2533 https://www.scottishmedicines.org.uk/media/7701/azacitidine-onureg-final-june-2023-updated-270623-for-website.pdf	15/08/2023
baricitinib 2mg, 4mg film-coated tablets (Olumiant®)	2572	For the treatment of severe alopecia areata in adult patients.	Not routinely available as not recommended for use in NHS Scotland, SMC 2572 https://www.scottishmedicines.org.uk/media/7756/baricitinib-olumiant-final-july-2023-for-website.pdf	15/08/2023
belantamab mafodotin 100mg powder for concentrate for solution for infusion (Blenrep®)	2597	As monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2597 https://www.scottishmedicines.org.uk/media/8029/belantamab-blenrep-final-dec-2023-for-website.pdf	16/01/2024
belzutifan 40mg film-coated tablets (Welireg®)	2587	Treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for VHL associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	17/10/2023

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bimekizumab 160mg solution for injection in pre-filled syringe, pre-filled pen (Bimzelx®)	2605	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). SMC restriction: Use in patients with active psoriatic arthritis who have not responded adequately to two conventional DMARDs, given either alone or in combination.	Routinely available in line with national guidance, SMC 2605 https://www.scottishmedicines.org.uk/media/7939/bimekizumab-bimzelx-abb-final-oct-2023-for-website.pdf Updates decision 21/11/23	20/02/2024
bimekizumab 160mg solution for injection in pre-filled syringe, pre-filled pen (Bimzelx®)	2616	Axial spondyloarthritis: - for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs) - for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy	Routinely available in line with national guidance, SMC 2616 https://www.scottishmedicines.org.uk/media/7988/bimekizumab-bimzelx-abb-final-nov-2023-for-website.pdf Updates decision 19/12/23	20/02/2024
brexucabtagene autoleucel 0.4 – 2 × 10 ⁸ cells dispersion for infusion (Tecartus®)	2548	Treatment of adults 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).	Routinely available from a specialist centre in another health board	17/10/2023
cabozantinib 20mg, 40mg, 60mg film-coated tablets (Cabometyx®)	2590	As monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to radioactive iodine (RAI) who have progressed during or after prior systemic therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2590 https://www.scottishmedicines.org.uk/media/8107/cabozantinib-cabometyx-final-jan-2024-for-website.pdf	20/02/2024

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cemiplimab 350mg concentrate for solution for infusion (Libtayo®)	2584	As monotherapy for the treatment of adults with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation.	Routinely available in line with national guidance, SMC 2584 https://www.scottishmedicines.org.uk/media/7989/cemiplimab-libtayo-final-nov-2023-for-website.pdf	19/12/2023
cipaglucosidase alfa 105mg powder for concentrate for solution for infusion (Pombiliti®)	2606	As a long-term enzyme replacement therapy used in combination with the enzyme stabiliser miglustat for the treatment of adults with late-onset Pompe disease (acid α -glucosidase [GAA] deficiency).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/12/2023
crizotinib 200mg, 250mg hard capsules (Xalkori®)	2621	As monotherapy for the treatment of paediatric patients (age ≥ 6 to < 18 years) with: - relapsed or refractory systemic anaplastic lymphoma kinase (ALK) positive anaplastic large cell lymphoma (ALCL) - recurrent or refractory anaplastic lymphoma kinase (ALK) positive unresectable inflammatory myofibroblastic tumour (IMT)	Not routinely available as not recommended for use in NHS Scotland, SMC 2621 https://www.scottishmedicines.org.uk/media/7816/crizotinib-xalkori-non-sub-final-august-2023-for-website.pdf	19/09/2023
dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®)	2577	In adults for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) $> 40\%$.	Routinely available in line with national guidance, SMC 2577 https://www.scottishmedicines.org.uk/media/7757/dapagliflozin-forxiga-abb-final-july-2023-for-website.pdf	15/08/2023
daratumumab 20mg/mL concentrate for solution for infusion, 1,800mg solution for injection (Darzalex®)	2536	In combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).	Routinely available in line with national guidance, SMC 2536 https://www.scottishmedicines.org.uk/media/7817/daratumumab-darzalex-final-august-2023-for-website.pdf	19/09/2023
darolutamide 300mg film-coated tablets (Nubeqa®)	2604	Treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.	Routinely available in line with national guidance, SMC 2604 https://www.scottishmedicines.org.uk/media/7870/darolutamide-nubeqa-resub-final-sept-2023-for-website.pdf Updates decision 17/10/23	19/12/2023

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degarelix 80mg, 120mg injection (Firmagon®)	2625	- for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy - as neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer	Routinely available in line with national guidance, SMC 2625 https://www.scottishmedicines.org.uk/media/7991/degarelix-firmagon-abb-final-nov-2023-for-website.pdf Updates decision 19/12/23	20/02/2024
deucravacitinib 6mg film-coated tablets (Sotyktu®)	2581	For the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/12/2023
difelikefalin 50micrograms/mL solution for injection (Kaprivia®)	2623	Treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis. SMC restriction: for use in patients with an inadequate response to best supportive care for reducing itch.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/02/2024
dupilumab 300mg solution for injection in pre-filled syringe, pre-filled pen (Dupixent®)	2598	For the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/02/2024
durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®)	2582	In combination with gemcitabine and cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer.	Routinely available in line with national guidance, SMC 2582 https://www.scottishmedicines.org.uk/media/7940/durvalumab-imfinzi-final-oct-2023-for-website.pdf Updates decision 21/11/23	19/12/2023

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efgartigimod alfa 20mg/mL concentrate for solution for infusion (Vyvgart®)	2561	As an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.	Not routinely available as not recommended for use in NHS Scotland, SMC 2561 https://www.scottishmedicines.org.uk/media/7931/efgartigimod-alfa-vyvgart-final-oct-2023-amended-251023-for-website.pdf	21/11/2023
empagliflozin 10mg film-coated tablet (Jardiance®)	2523	In adults for the treatment of symptomatic chronic heart failure with preserved ejection fraction (left ventricular ejection fraction [LVEF] >40%).	Not routinely available as there is a local preference for alternative medicines Updates decision 16/05/23	15/08/2023
fenfluramine 2.2mg/mL oral solution (Fintepla®)	2569	For the treatment of seizures associated with Dravet syndrome as an add-on to other anti-epileptic medicines for patients 2 years of age and older. SMC restriction: as add-on therapy for treating seizures associated with Dravet syndrome where seizures have not been controlled in people aged 2 years and older after trying two or more anti-seizure medicines.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	17/10/2023
ibrutinib 140mg, 280mg, 420mg film-coated tablets (Imbruvica®)	2543	In combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).	Routinely available in line with national guidance, SMC 2543 https://www.scottishmedicines.org.uk/media/7878/ibrutinib-imbruvica-final-august-2023-for-website-amended-october-2023.pdf Updates decision 19/09/23	21/11/2023

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icosapent ethyl 998mg soft capsules (Vazkepa®)	2602	<p>To reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (≥ 1.7mmol/L) and</p> <ul style="list-style-type: none"> - established cardiovascular disease, or - diabetes, and at least one other cardiovascular risk factor. <p>SMC restriction: use as secondary prevention in patients treated with a stable dose of statins, low-density lipoprotein (LDL) cholesterol levels > 1.04mmol/L and ≤ 2.60mmol/L, raised fasting triglycerides (≥ 1.7mmol/L) and with established cardiovascular disease defined as a history of any of the following:</p> <ul style="list-style-type: none"> - Acute coronary syndrome (ACS) (such as myocardial infarction (MI) or unstable angina needing hospitalisation) - Coronary or other arterial revascularisation procedures - Coronary heart disease - Ischaemic stroke - Peripheral arterial disease 	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/08/2023
ivosidenib 250mg film-coated tablet (Tibsovo®)	2615	<p>In combination with azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.</p>	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/03/2024

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loncastuximab tesirine 10mg powder for concentrate for solution for infusion (Zynlonta®)	2609	As monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy. SMC restriction: where chimeric antigen receptor (CAR) T-cell therapy is unsuitable, not tolerated or ineffective.	Routinely available in line with national guidance, SMC 2609 https://www.scottishmedicines.org.uk/media/8110/loncastuximab-tesirine-zynlonta-final-jan-2024-for-website.pdf Updates decision 20/02/24	16/04/2024
lumasiran 94.5mg/0.5 mL solution for injection (Oxlumo®)	2639	Treatment of primary hyperoxaluria type 1 (PH1) in all age groups.	Not routinely available as not recommended for use in NHS Scotland, SMC 2639 https://www.scottishmedicines.org.uk/media/7993/lumasiran-oxlumo-non-sub-final-nov-2023-for-website.pdf	19/12/2023
lutetium (¹⁷⁷ Lu) vipivotide tetraxetan 1,000MBq/mL solution for injection or infusion (Pluvicto®)	2517	Treatment of adult patients with prostate specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy or who are not medically suitable for taxanes.	Not routinely available as not recommended for use in NHS Scotland, SMC 2517 https://www.scottishmedicines.org.uk/media/7871/lutetium-177-lu-vipivotide-tetraxetan-pluvicto-final-updated-310823-for-website.pdf	17/10/2023
maribavir 200mg film-coated tablets (Livtencity®)	2576	Treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). Consideration should be given to official guidance on the appropriate use of antiviral agents.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	17/10/2023

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mercaptamine 25mg, 75mg gastro-resistant hard capsules (Procysbi®)	2571	Treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure.	Not routinely available as not recommended for use in NHS Scotland, SMC 2571 https://www.scottishmedicines.org.uk/media/7932/mercaptamine-procysbi-resub-final-oct-2023-amended-031123-for-website.pdf	21/11/2023
mosunetuzumab 1mg, 30mg concentrate for solution for infusion (Lunsumio®)	2542	As monotherapy for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies.	Not routinely available as not recommended for use in NHS Scotland, SMC 2542 https://www.scottishmedicines.org.uk/media/7819/mosunetuzumab-lunsumio-final-august-2023-for-website.pdf	19/09/2023
nirmatrelvir 150mg plus ritonavir 100mg film coated tablets (Paxlovid®)	2557	Treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19. SMC restriction: patients with any of the following: - increased risk for progression to severe COVID-19, as defined in section 5 of NICE final guidance - age 70 years and over - a body mass index (BMI) of 35 kg/m ² or more - diabetes - heart failure	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/03/2024
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	2519	In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) with tumour cell programmed death ligand 1 (PD-L1) expression ≥1%.	Routinely available in line with national guidance, SMC 2519 https://www.scottishmedicines.org.uk/media/7612/nivolumab-opdivo-final-may-2023-for-website.pdf Updates decision 20/06/23	17/10/2023

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nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	2619	In combination with platinum-based chemotherapy for the neoadjuvant treatment of resectable (tumours ≥4 cm or node positive) non-small cell lung cancer in adults.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/12/2023
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	2620	In combination with ipilimumab for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell programmed death ligand (PD-L1) expression ≥ 1%.	Not routinely available as not recommended for use in NHS Scotland, SMC 2620 https://www.scottishmedicines.org.uk/media/7820/nivolumab-opdivo-non-sub-final-august-2023-for-website.pdf	19/09/2023
olaparib 100mg, 150mg film-coated tablets (Lynparza®)	2518	As monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline BRCA1/2-mutations who have human epidermal growth factor receptor 2 (HER2)-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.	Routinely available in line with national guidance, SMC 2518 https://www.scottishmedicines.org.uk/media/7876/olaparib-lynparza-final-sept-2023-amended-210923-for-website.pdf Updates decision 17/10/23	16/04/2024
olaparib 100mg, 150mg film-coated tablets (Lynparza®)	2617	In combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/03/2024
osilodrostat 1mg, 5mg, 10mg film-coated tablets (Isturisa®)	2640	Treatment of endogenous Cushing's syndrome in adults.	Not routinely available as not recommended for use in NHS Scotland, SMC 2640 https://www.scottishmedicines.org.uk/media/7995/osilodrostat-isturisa-non-sub-final-nov-2023-for-website.pdf	19/12/2023
patiromer sorbitex calcium 8.4g, 16.8g powder for oral suspension (Veltassa®)	2568	Treatment of hyperkalaemia in adults. SMC restriction: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.	Not routinely available as there is a local preference for alternative medicines Updates decision 18/04/23	20/02/2024

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pegunigalsidase alfa 2mg/mL concentrate for solution for infusion (Elfabrio®)	2591	For long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry Disease (deficiency of alpha-galactosidase).	Not routinely available as not recommended for use in NHS Scotland, SMC 2591 https://www.scottishmedicines.org.uk/media/7933/pegunigalsidase-alfa-elfabrio-final-oct-2023-amended-111023-261023-for-website.pdf	21/11/2023
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	2526	As monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB or IIC melanoma and who have undergone complete resection.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	18/04/2023
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	2538	In combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, for the treatment of adults with locally advanced, or early stage triple-negative breast cancer (TNBC) at high risk of recurrence.	Routinely available in line with national guidance, SMC 2538 https://www.scottishmedicines.org.uk/media/7613/pembrolizumab-keytruda-final-may-2023-for-website.pdf Updates decision 20/06/23	15/08/2023

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pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	2589	<p>As monotherapy for adults with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in the following settings:</p> <ul style="list-style-type: none"> - treatment of unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy. <p>As monotherapy for the treatment of the following MSI-H or dMMR tumours in adults with:</p> <ul style="list-style-type: none"> - advanced or recurrent endometrial carcinoma, who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation; - unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy. <p>Restriction: pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if the cancer progresses.</p>	<p>Routinely available in line with local guidance.</p> <p>Note: advanced or recurrent endometrial carcinoma is not routinely available as the ADTC is waiting for further advice from local clinical experts.</p> <p>Updates decision 16/01/24</p>	19/03/2024
pitolisant 4.5mg, 18mg film-coated tablets (Wakix®)	2662	<p>To improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP).</p>	<p>Not routinely available as not recommended for use in NHS Scotland,</p> <p>SMC 2662</p> <p>https://www.scottishmedicines.org.uk/media/8164/pitolisant-wakix-non-sub-final-feb-2024-for-website.pdf</p>	19/03/2024
polatuzumab vedotin 30mg, 140mg powder for concentrate for solution for infusion (Polivy®)	2524	<p>In combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant (HSCT).</p>	<p>Routinely available in line with national guidance,</p> <p>SMC 2524</p> <p>https://www.scottishmedicines.org.uk/media/7703/polatuzumab-vedotin-polivy-reassessment-final-june-2023-for-website.pdf</p>	15/08/2023

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polatuzumab vedotin 30mg, 140mg powder for concentrate for solution for infusion (Polivy®)	2525	In combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). SMC restriction: patients with an International Prognostic Index (IPI) score of 2 to 5.	Routinely available in line with national guidance, SMC 2525 https://www.scottishmedicines.org.uk/media/7614/polatuzumab-vedotin-polivy-final-may-2023-for-website.pdf Updates decision 20/06/23	15/08/2023
Produodopa® 240mg/mL / 12mg/mL solution for infusion (foslevodopa/foscarbidopa)	2574	Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. SMC restriction: for use in patients not eligible for deep brain stimulation (DBS).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/03/2024
progesterone 200mg vaginal capsules (Utrogestan®)	2630	Prevention of preterm birth in women with a singleton pregnancy who have a short cervix (mid-trimester sonographic cervix ≤ 25 mm) and/or a history of spontaneous preterm birth.	Not routinely available as not recommended for use in NHS Scotland, SMC 2630 https://www.scottishmedicines.org.uk/media/7934/progesterone-vaginal-capsules-utrogestan-non-sub-final-oct-2023-for-website.pdf	21/11/2023
ravulizumab 300mg/3mL, 1100mg/11mL concentrate for solution for infusion (Ultomiris®)	2657	As an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.	Not routinely available as not recommended for use in NHS Scotland, SMC 2657 https://www.scottishmedicines.org.uk/media/8104/ravulizumab-ultomiris-gmg-non-sub-final-jan-2024-for-website.pdf	20/02/2024
ravulizumab 300mg/3mL, 1100mg/11mL concentrate for solution for infusion (Ultomiris®)	2658	Treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.	Not routinely available as not recommended for use in NHS Scotland, SMC 2658 https://www.scottishmedicines.org.uk/media/8105/ravulizumab-ultomiris-nmosd-non-sub-final-jan-2024-for-website.pdf	20/02/2024

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regorafenib 40mg film-coated tablets (Stivarga®)	2562	As monotherapy for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.	Routinely available in line with national guidance, SMC 2562 https://www.scottishmedicines.org.uk/media/7882/regorafenib-stivarga-final-sept-2023-amended-180923-for-website-amended-161023.pdf Updates decision 17/10/23	19/03/2024
rimegepant 75mg oral lyophilisate (Vydura®)	2521	For the acute treatment of migraine with or without aura in adults. SMC restriction: for patients who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol.	Routinely available in line with local guidance, Updates decision 16/05/23	20/06/2023
rimegepant 75mg oral lyophilisate (Vydura®)	2603	For the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month. SMC restriction: for patients with episodic migraine who have at least 4 migraine attacks per month, but fewer than 15 headache days per month and who have had prior failure on three or more migraine preventive treatments.	Routinely available in line with local guidance Updates decision 19/09/23	21/11/2023
risankizumab 600mg concentrate for solution for infusion, 360mg solution for injection (Skyrizi®)	2534	For the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.	Routinely available in line with national guidance, SMC 2534 https://www.scottishmedicines.org.uk/media/7935/risankizumab-skyrizi-abb-final-dec-2022-updated-250923-for-website.pdf Updates decision 21/11/23	19/12/2023

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ropeginterferon alfa-2b 250micrograms/0.5 mL solution for injection in pre-filled pen (Besremi®)	2563	As monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly.	Not routinely available as not recommended for use in NHS Scotland, SMC 2563 https://www.scottishmedicines.org.uk/media/7704/ropeginterferon-alfa-2b-besremi-resub-final-june-2023-for-website.pdf	15/08/2023
satralizumab 120mg solution for injection in pre-filled syringe (Enspryng®)	2663	As a monotherapy or in combination with immunosuppressive therapy (IST) for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in adult and adolescent patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive.	Not routinely available as not recommended for use in NHS Scotland, SMC 2663 https://www.scottishmedicines.org.uk/media/8165/satralizumab-enspryng-non-sub-final-feb-2024-for-website.pdf	19/03/2024
secukinumab 150mg, 300mg solution for injection in pre-filled pen, pre-filled syringe (Cosentyx®)	2592	For the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. SMC restriction: for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/02/2024
selpercatinib 40mg, 80mg hard capsules (Retsevmo®)	2573	Monotherapy for the treatment of adults with advanced rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor. SMC restriction: for use in treatment-naïve patients who have not previously received a RET-inhibitor or any other systemic treatments for their advanced stage of disease.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
selumetinib 10mg, 25mg hard capsules (Koselugo®)	2540	As monotherapy for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above.	Not routinely available as not recommended for use in NHS Scotland, SMC 2540 https://www.scottishmedicines.org.uk/media/7754/selumetinib-koselugo-final-july-2023-for-website.pdf	15/08/2023
semaglutide, 0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg FlexTouch solution for injection in pre-filled pen (Wegovy®)	2497	As an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of: - $\geq 30\text{kg/m}^2$ (obesity), or - $\geq 27\text{kg/m}^2$ to $< 30\text{kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity. SMC restriction: BMI of $\geq 30\text{kg/m}^2$ * in the presence of at least one weight-related comorbidity. Patients should be treated in a specialist weight management service. *a lower BMI cut-off may be more appropriate for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	17/10/2023
setmelanotide 10mg/mL solution for injection (Imcivree®)	2647	Treatment of obesity and the control of hunger associated with genetically confirmed Bardet Biedl syndrome (BBS) in adults and children 6 years of age and above.	Not routinely available as not recommended for use in NHS Scotland, SMC 2647 https://www.scottishmedicines.org.uk/media/8027/setmelanotide-imcivree-non-sub-final-dec-2023-for-website.pdf	16/01/2024
tafamidis 61mg soft capsules (Vyndaqel®)	2585	For the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023

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tafasitamab 200mg powder for concentrate for solution for infusion (Minjuvi®)	2522	In combination with lenalidomide followed by tafasitamab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).	Not routinely available as not recommended for use in NHS Scotland, SMC 2522 https://www.scottishmedicines.org.uk/media/7566/tafasitamab-minjuvi-final-april-2023-for-website.pdf	16/05/2023
talazoparib 0.25mg, 1mg hard capsules (Talzenna®)	2607	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 the ADTC is waiting for further advice from local clinical experts	19/03/2024
tezepelumab 210mg solution for injection in pre-filled syringe (Tezspire®)	2541	As an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment. SMC restriction: in adults and adolescents 12 years and older who either (i) experienced at least three exacerbations in the previous year and are not receiving maintenance treatment with oral corticosteroids or (ii) have blood eosinophils ≥ 150 cells/microlitre and are receiving maintenance treatment with oral corticosteroids.	Routinely available in line with national guidance, SMC 2541 https://www.scottishmedicines.org.uk/media/7758/tezepelumab-tezspire-final-july-2023-amended-020823-for-website.pdf Updates decision 15/08/23	20/02/2024

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tixagevimab 150mg/mL plus cilgavimab 150mg/mL solution for injection (Evusheld®)	2580	Pre-exposure prophylaxis of COVID-19 in adults who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and: - who are unlikely to mount an adequate immune response to COVID-19 vaccination or - for whom COVID-19 vaccination is not recommended	Not routinely available as not recommended for use in NHS Scotland, NICE TA900 https://www.nice.org.uk/guidance/TA900	20/06/2023
trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®)	2545	As monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens. SMC restriction: in patients who have received one prior anti-HER2-based regimen.	Routinely available in line with national guidance, SMC 2545 https://www.scottishmedicines.org.uk/media/7509/trastuzumab-deruxtecan-enhertu-final-march-amended-030423-for-website.pdf Updates decision 18/04/23	15/08/2023
trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®)	2608	As monotherapy for the treatment of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.	Routinely available in line with national guidance, SMC 2608 https://www.scottishmedicines.org.uk/media/7996/trastuzumab-deruxtecan-enhertu-final-nov-2023-amended-011223-for-website.pdf Updates decision 19/12/23	16/01/2024
treosulfan 1g, 5g powder for solution for infusion (Trecondi®)	2527	In combination with fludarabine as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients with malignant and non-malignant diseases, and in paediatric patients older than one month with malignant diseases. SMC restriction: in patients with malignant disease for whom a reduced intensity conditioning regimen is required.	Routinely available from a specialist centre in another health board	20/06/2023

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upadacitinib 15mg, 30mg, 45mg prolonged release tablets (Rinvoq®)	2575	For the treatment of adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent, or for whom such therapies are not advisable.	Routinely available in line with national guidance, SMC 2575 https://www.scottishmedicines.org.uk/media/7611/upadacitinib-rinvoq-abbreviated-final-may-2023-for-website.pdf	20/06/2023
voclosporin 7.9mg soft capsule (Lupkynis®)	2570	In combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis.	Not routinely available as there is a local preference for alternative medicines Updates decision 17/10/23	21/11/2023
vutrisiran 25mg solution for injection in prefilled syringe (Amvuttra®)	2596	For the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.	Routinely available in line with national guidance, SMC 2596 https://www.scottishmedicines.org.uk/media/7824/vutrisiran-amvuttra-abb-final-aug-2023-for-website-amended-2508.pdf Updates decision 19/09/23	21/11/2023
zanubrutinib 80mg hard capsules (Brukinsa®)	2600	As monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL). SMC restriction: For adults with CLL in whom chemo-immunotherapy is unsuitable.	Routinely available in line with national guidance, SMC 2600 https://www.scottishmedicines.org.uk/media/7866/zanubrutinib-brukinsa-abb-final-sept-2023-for-website.pdf Updates decision 17/10/23	21/11/2023