

This document summarises the decisions of the NHS Grampian Formulary Group for Scottish Medicines Consortium (SMC) advice published April 2022 to March 2023.

For the latest Formulary Group decisions see the <u>Grampian Area Formulary</u> website.

# February 2025

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
abemaciclib 50mg, 100mg, 150mg film-coated tablets (Verzenios®)	<u>2494</u>	In combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative, node-positive early breast cancer at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone- releasing hormone (LHRH) agonist.	Routinely available in line with national guidance, SMC 2494 https://www.scottishmedicines.org.uk/media/7296/abemaci clib-verzenios-final-nov-2022-for-website.pdf Updates decision 20/12/22	16/05/2023
abrocitinib 50mg, 100mg, 200mg film coated tablets (Cibinqo®)	- <u>2431</u>	For the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. <b>SMC restriction:</b> for use in patients who have not responded to, or have lost response to, at least one systemic immunosuppressant therapy, or in whom these are contraindicated or not tolerated.	Routinely available in line with national guidance, SMC 2431 https://www.scottishmedicines.org.uk/media/6931/abrocitin ib-cibinqo-final-may-2022-for-website.pdf Updates decision 21/06/22	20/09/2022
alpelisib 50mg, 150mg, 200mg film- coated tablets (Piqray®)	<u>2481</u>	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-based therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2481 https://www.scottishmedicines.org.uk/media/7292/alpelisib- piqray-final-nov-2022-for-website.pdf	20/12/2022
apalutamide 60mg film-coated tablets (Erleada®)	<u>2472</u>	Treatment of adults with metastatic hormone- sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).	Routinely available in line with national guidance, SMC 2472 https://www.scottishmedicines.org.uk/media/7096/apaluta mide-erleada-final-august-2022-for-website.pdf Updates decision 20/09/22	21/02/2023

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asciminib 20mg, 40mg film-coated tablets (Scemblix <sup>®</sup> )	<u>2482</u>	For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and without a known T315I mutation.	Routinely available in line with national guidance, SMC 2482 https://www.scottishmedicines.org.uk/media/7245/ascimini b-scemblix-final-oct-2022-amended-171122-for-website.pdf Updates decision 15/11/22	16/05/2023
atezolizumab 840mg, 1,200mg concentrate for solution for infusion (Tecentriq®)	<u>2492</u>	As monotherapy as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC staging system) non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on ≥50% of tumour cells and whose disease has not progressed following platinum-based adjuvant chemotherapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	16/08/2022
belimumab 120mg, 400mg powder for concentrate for solution for infusion (Benlysta®)	<u>2477</u>	Add-on therapy in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy. <b>SMC restriction</b> : in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA- SLEDAI) score ≥10.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/11/2022
belimumab 120mg, 400mg powder for concentrate for solution for infusion, 200mg solution for injection in pre-filled pen (Benlysta®)	<u>2483</u>	In combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis.	Not routinely available as not recommended for use in NHS Scotland, SMC 2483 https://www.scottishmedicines.org.uk/media/6791/belimum ab-benlysta-non-sub-final-march-2022-for-website.pdf	19/04/2022

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
belimumab 200mg solution for injection in pre filled pen or pre-filled syringe (Benlysta®)	<u>2530</u>	Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. <b>SMC restriction:</b> in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA- SLEDAI) score ≥10.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/11/2022
Bijuve <sup>®</sup> 1mg/100mg capsules (estradiol/micronised progesterone)	<u>2502</u>	Continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/09/2022
brolucizumab 120mg/mL solution for injection in pre-filled syringe (Beovu®		In adults for the treatment of visual impairment due to diabetic macular oedema. <b>SMC restriction:</b> treatment of visual impairment due to diabetic macular oedema in adults with best corrected visual acuity 75 Early Treatment Diabetic Retinopathy Study letters or less at baseline.	Not routinely available as there is a local preference for alternative medicines Updates decision 18/10/22	20/12/2022

**NHS Grampian decision** Date of decision **Condition being treated** Name Unique identifier bulevirtide 2mg powder for solution 2520 For the treatment of chronic hepatitis delta virus Routinely available in line with national guidance, 20/06/2023 for injection (Hepcludex<sup>®</sup>) (HDV) infection in plasma (or serum) HDV-RNA SMC 2520 positive adult patients with compensated liver https://www.scottishmedicines.org.uk/media/7451/bulevirti disease. de-hepcludex-final-feb-2023-for-website.pdf **SMC restriction**: to use in patients with evidence Updates decision 21/03/23 of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based therapy or who are ineligible to receive interferon-based therapy due to intolerance or contra-indication. carfilzomib 10mg, 30mg, 60mg 2484 In combination with daratumumab and Not routinely available as not recommended for use in NHS 19/04/2022 powder for solution for infusion dexamethasone for the treatment of adult Scotland. patients with multiple myeloma who have SMC 2484 (Kyprolis<sup>®</sup>) https://www.scottishmedicines.org.uk/media/6792/carfilzo received at least one prior therapy. mib-kyprolis-non-sub-final-march-2022-for-website.pdf Treatment of acute COVID-19 infection. casirivimab 120mg/mL plus 2553 This medicine is now withdrawn from use/discontinued 15/08/2023 imdevimab 120mg/mL solution for Updates decision 18/04/23 injection or infusion (Ronapreve<sup>®</sup>) As monotherapy for the first-line treatment of Not routinely available as not recommended for use in NHS 17/05/2022 cemiplimab 350mg concentrate for 2489 adult patients with non-small cell lung cancer Scotland, solution for infusion (Libtavo<sup>®</sup>) (NSCLC) expressing PD-L1 (in  $\geq$ 50% tumour cells), SMC 2489 https://www.scottishmedicines.org.uk/media/6860/cemipli with no EGFR, ALK or ROS1 aberrations, who have: - locally advanced NSCLC who are not candidates mab-libtayo-non-sub-final-april-2022-for-website.pdf for definitive chemoradiation, or - metastatic NSCLC crizanlizumab 10mg/mL concentrate For the prevention of recurrent vaso-occlusive 2438 The MHRA has recommended that the marketing 20/02/2024 crises in sickle cell disease patients aged 16 years for solution for infusion (Adakveo<sup>®</sup>) authorisation of the medicine be revoked... and older. It can be given as an add-on therapy to On 10 January 2024 the UK conditional marketing hydroxycarbamide or as monotherapy in patients authorisation for crizanlizumab was revoked due to lack of for whom hydroxycarbamide is inappropriate or therapeutic efficacy as determined by MHRA Updates decision 16/08/22 inadequate.

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dapagliflozin 10mg film-coated tablets (Forxiga®)	<u>2428</u>	In adults for the treatment of chronic kidney disease. <b>SMC restriction:</b> - in patients with an estimated glomerular filtration rate of ≥25 to ≤75 mL/min/1.73m <sup>2</sup> at treatment initiation, and - are receiving an angiotensin converting enzyme inhibitor or angiotensin receptor blocker (unless these are not tolerated or contraindicated), and - have a urine albumin creatinine ratio of at least 23mg/mmol, or type 2 diabetes mellitus or both	Routinely available in line with national guidance, SMC 2428 https://www.scottishmedicines.org.uk/media/6871/dapaglifl ozin-forxiga-final-april-2022-amended-290422-for- website.pdf Updates decision 17/05/22	16/08/2022
daratumumab 1,800mg solution for injection (Darzalex <sup>®</sup> )	<u>2447</u>	In combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic light chain (AL) amyloidosis.	Routinely available in line with national guidance, SMC 2447 https://www.scottishmedicines.org.uk/media/7045/daratum umab-darzalex-final-july-2022-for-website.pdf Updates decision 16/08/22	17/01/2023
daratumumab 20mg/mL concentrate for solution for infusion, 1,800mg solution for injection (Darzalex®)	<u>2416</u>	In combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.	Not routinely available as not recommended for use in NHS Scotland, SMC 2416 https://www.scottishmedicines.org.uk/media/6870/daratum umab-darzelex-final-april-2022-for-website.pdf	17/05/2022

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delafloxacin 450mg tablets, 300mg powder for concentrate for solution for infusion (Quofenix®)	<u>2453</u>	Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of this infection. <b>SMC restriction:</b> patients with suspected or confirmed polymicrobial infection following treatment failure or when standard antibacterial therapies are not suitable. Delafloxacin should be used on the advice of local microbiologists or specialists in infectious disease. Consideration should be given to official guidance on the appropriate use of antibacterial agents.	Routinely available in line with national guidance, SMC 2453 https://www.scottishmedicines.org.uk/media/6983/delaflox acin-quofenix-final-june-2022-for-website.pdf Updates decision 16/08/22	21/02/2023
Drovelis <sup>®</sup> 14.2mg/3mg film-coated tablets (estetrol/drospirenone)	<u>2564</u>	Oral contraception.	Not routinely available as not recommended for use in NHS Scotland, SMC 2564 https://www.scottishmedicines.org.uk/media/7355/estetrol- drovelis-non-sub-final-dec-2022-for-website.pdf	17/01/2023
Ducressa® 5mg/mL / 1mg/mL eye drops solution (levofloxacin/dexamethasone)	<u>2511</u>	For prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/11/2022
enfortumab vedotin 20mg, 30mg powder for concentrate for solution for infusion (Padcev®)	<u>2505</u>	As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor.	Not routinely available as not recommended for use in NHS Scotland, SMC 2505 https://www.scottishmedicines.org.uk/media/6984/enfortu mab-vedotin-padcev-non-sub-final-june-2022-for- website.pdf	16/08/2022

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eptinezumab 100mg concentrate for solution for infusion (Vyepti®)	<u>2547</u>	For the prophylaxis of migraine in adults who have at least 4 migraine days per month. <b>SMC restriction:</b> 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 21/02/23	20/06/2023
esketamine 28mg nasal spray, solution (Spravato®)	<u>2539</u>	Co-administered with oral antidepressant therapy, in adults with a moderate to severe episode of Major Depressive Disorder, as acute short-term treatment, for the rapid reduction of depressive symptoms, which according to clinical judgement constitute a psychiatric emergency.	Not routinely available as not recommended for use in NHS Scotland, SMC 2539 https://www.scottishmedicines.org.uk/media/7204/esketam inie-spravato-non-sub-final-oct-2022docxfor-website.pdf	15/11/2022
faricimab 120mg/mL solution for injection (Vabysmo®)	<u>2499</u>	For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO). <b>SMC restriction</b> : treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) of 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.	Routinely available in line with national guidance, SMC 2499 https://www.scottishmedicines.org.uk/media/7205/faricima b-vabysmo-final-oct-2022docxfor-website.pdf Updates decision 15/11/22	20/12/2022
faricimab 120mg/mL solution for injection (Vabysmo®)	<u>2512</u>	For the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD).	Routinely available in line with national guidance, SMC 2512 https://www.scottishmedicines.org.uk/media/7293/faricima b-vabysmo-abb-final-nov-2022-for-website.pdf	20/12/2022
fedratinib 100mg hard capsules (Inrebic®)	<u>2462</u>	For the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.	Routinely available in line with national guidance, SMC 2462 https://www.scottishmedicines.org.uk/media/6793/fedratini b-inrebic-abbreviated-final-march-2022-for-website.pdf Updates decision 19/04/22	20/09/2022

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ferric maltol 30mg hard capsules (Feraccru®)	<u>2500</u>	In adults for the treatment of iron deficiency.	Not routinely available as not recommended for use in NHS Scotland, SMC 2500 https://www.scottishmedicines.org.uk/media/7361/ferric- maltol-feraccru-resub-final-dec-2022-updated-12123-for- website.pdf	17/01/2023
filgotinib 100mg, 200mg film-coated tablets (Jyseleca®)	<u>2467</u>	For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.	Routinely available in line with national guidance, SMC 2467 https://www.scottishmedicines.org.uk/media/6862/filgotinib- jyseleca-abbreviated-final-april-2022-for-website.pdf Updates decision 17/05/22	20/09/2022
filgotinib 100mg, 200mg film-coated tablets (Jyseleca®)	<u>2475</u>	For the treatment of moderate to severe 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). Filgotinib may be used as monotherapy or in combination with methotrexate. <b>SMC restriction</b> : in adults with moderate disease (a disease activity score [DAS28] of 3.2 to 5.1) when intensive therapy with 2 or more conventional DMARDs has not controlled the disease well enough, in combination with methotrexate or as monotherapy when methotrexate is contraindicated.	Routinely available in line with local guidance Updates decision 18/10/22	16/05/2023
finerenone 10mg, 20mg film-coated tablets (Kerendia®)	<u>2486</u>	For the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.	Routinely available in line with local guidance, ADVICE ARCHIVED, replaced by FG advice published 03/06/2024 (FG meeting 21/05/2024). Updates decision 15/11/22	21/05/2024

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
ibrutinib 140mg, 280mg, 420mg, 560mg film coated tablets (Imbruvica®)	<u>2485</u>	In combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia.	Not routinely available as not recommended for use in NHS Scotland, SMC 2485 https://www.scottishmedicines.org.uk/media/6794/ibrutinib- imbruvica-non-sub-march-2022-for-website.pdf	19/04/2022
imlifidase 11mg powder for concentrate for solution for infusion (Idefirix®)	<u>2445</u>	For desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.	Routinely available from a specialist centre in another health board Updates decision 20/09/22	18/10/2022
ixekizumab 80mg solution for injection in pre-filled syringe or pen (Taltz®)	<u>2440</u>	Treatment of adult patients with: - active ankylosing spondylitis who have responded inadequately to conventional therapy - 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 to nonsteroidal anti- inflammatory drugs (NSAIDs)	Not routinely available as not recommended for use in NHS Scotland, SMC 2440 https://www.scottishmedicines.org.uk/media/6932/ixekizum ab-taltz-final-may-2022-for-website.pdf	21/06/2022
lenvatinib 4mg, 10mg hard capsules (Kisplyx <sup>®</sup> )	<u>2476</u>	Treatment of adults with advanced renal cell carcinoma (RCC), in combination with pembrolizumab, as first-line treatment. <b>SMC restriction:</b> treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2476 https://scottishmedicines.org.uk/media/6933/lenvatinib- kisplyx-abb-final-may-2022-for-website.pdf Updates decision 21/06/22	19/11/2024

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liraglutide 6mg/mL solution for injection in pre-filled pen (Saxenda®)	<u>2455</u>	SMC restriction: As an adjunct to a reduced- calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of BMI ≥35kg/m <sup>2</sup> * (obesity class II and above) with: <ul> <li>Non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes which is defined as having either:</li> <li>Fasting plasma glucose level of 5.5 to</li> <li>6.9mmol/L or</li> <li>HbA1c of 6.0 to 6.4% (42 to 47mmol/mol), and</li> <li>High risk of cardiovascular disease (CVD):</li> <li>Total cholesterol &gt;5mmol/L, or</li> <li>High-density lipoprotein (HDL) &lt;1.0mmol/L for men and &lt;1.3mmol/L for women, or</li> <li>Systolic blood pressure (SBP) &gt;140mmHg</li> </ul> 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 local implementation plans are being developed Updates decision 17/05/22	18/06/2024
mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen, pre- filled syringe (Nucala <sup>®</sup> )	<u>2488</u>	As add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non- haematologic secondary cause.	Not routinely available as not recommended for use in NHS Scotland, SMC 2488 https://www.scottishmedicines.org.uk/media/6855/mepoliz umab-nucala-hs-non-sub-final-april-2022-for-website.pdf	17/05/2022

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mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen, pre- filled syringe (Nucala®)	<u>2490</u>	As an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).	Not routinely available as not recommended for use in NHS Scotland, SMC 2490 https://www.scottishmedicines.org.uk/media/6864/mepoliz umab-nucala-egpa-non-sub-final-april-2022-for-website.pdf	17/05/2022
mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen, pre- filled syringe (Nucala®)	<u>2491</u>	As an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control.	Not routinely available as not recommended for use in NHS Scotland, SMC 2491 https://www.scottishmedicines.org.uk/media/6856/mepoliz umab-nucala-scr-non-sub-final-april-2022-for-website.pdf	17/05/2022
micronised progesterone 100mg capsules (Utrogestan®)	<u>2529</u>	For adjunctive use with oestrogen in post- menopausal women with an intact uterus, as hormone replacement therapy (HRT). <b>Restriction:</b> 1) second-line in women who suffer or have suffered moderate or severe progestogenic side- effects when using combined HRT preparations or with other progestogens as part of HRT, contraception or bleeding control 2) as an alternative progestogen in women with an increased risk of breast cancer, cardiovascular disease (CVD) or venous thromboembolism (VTE) and do not have an absolute contra-indication to HRT	Routinely available in line with local guidance	20/12/2022
mobocertinib 40mg hard capsules (Exkivity®)	2516	As monotherapy for the treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received prior platinum-based chemotherapy.	The MHRA has recommended that the marketing authorisation of the medicine be revoked., The official withdrawal of the conditional marketing authorisation will occur on 8th March 2024. Updates decision 17/01/23	20/02/2024

NHS Grampian Formulary Group Decisions for SMC advice published April 2022 to March 2023	
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nintedanib 100mg, 150mg soft capsules (Ofev®)	<u>2513</u>	In adults for the treatment of idiopathic pulmonary fibrosis (IPF). <b>SMC restriction</b> : for use in patients with a predicted forced vital capacity (FVC) >80%.	Routinely available in line with national guidance, SMC 2513 https://www.scottishmedicines.org.uk/media/7449/ninteda nib-ofev-resub-final-feb-2023-for-website.pdf Updates decision 21/03/23	19/09/2023
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	<u>2429</u>	As monotherapy for the adjuvant treatment of adult patients with completely resected oesophageal or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy.	Routinely available in line with national guidance, SMC 2429 https://www.scottishmedicines.org.uk/media/6857/nivolum ab-opdivo-final-april-2022-for-website.pdf Updates decision 17/05/22	18/10/2022
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	<u>2458</u>	In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with HER2-negative advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.	Routinely available in line with national guidance, SMC 2458 https://www.scottishmedicines.org.uk/media/7091/nivolum ab-opdivo-final-aug-2022-for-website.pdf Updates decision 20/09/22	18/04/2023
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	<u>2503</u>	As monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥1%, who are at high risk of recurrence after undergoing radical resection of MIUC.	Routinely available in line with national guidance, SMC 2503 https://www.scottishmedicines.org.uk/media/7404/nivolum ab-opdivo-final-jan-2023-for-website.pdf Updates decision 21/02/23	21/05/2024
oritavancin 400mg powder for concentrate for solution for infusion (Tenkasi®)	<u>2285</u>	Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. <b>SMC restriction:</b> patients with confirmed or suspected methicillin-resistant Staphylococcus aureus (MRSA) infection who are eligible for early discharge. Use should be on the advice of local microbiologists or specialists in infectious disease.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time, Updates decision 17/05/22	21/06/2022

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ozanimod 0.23mg, 0.46mg, 0.92mg hard capsules (Zeposia®)	<u>2478</u>	For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.	Routinely available in line with national guidance, SMC 2478 https://www.scottishmedicines.org.uk/media/7139/ozanimo d-zeposia-final-sept-2022-for-website.pdf Updates decision 18/10/22	16/05/2023
Palforzia <sup>®</sup> 0.5mg, 1mg, 10mg, 20mg, 100mg oral powder in capsules for opening, 300mg oral powder in sachet (defatted powder of Arachis hypogaea L., semen (peanuts))	<u>2487</u>	Treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. Palforzia® may be continued in patients 18 years of age and older. Palforzia® should be used in conjunction with a peanut-avoidant diet.	Not routinely available as not recommended for use in NHS Scotland, SMC 2487 https://www.scottishmedicines.org.uk/media/7215/defatted- powder-of-arachis-hypogaea-I-semen-peanuts-palforzia-final- sept-2022-amended-071122-for-website.pdf	18/10/2022
pegcetacoplan 1,080mg solution for infusion (Aspaveli®)	<u>2451</u>	In the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months. <b>SMC restriction</b> : under the advice of the national PNH service.	Routinely available in line with national guidance, SMC 2451 https://www.scottishmedicines.org.uk/media/6985/pegceta coplan-aspaveli-final-june-2022-for-website.pdf Updates decision 16/08/22	16/05/2023
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2420</u>	In combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS≥10. <b>SMC restriction:</b> treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2420 https://www.scottishmedicines.org.uk/media/6872/pembrol izumab-keytruda-final-april-2022-amended-4522-for- website.pdf SMC advice relating to patients with HER2-negative gastro- oesophageal adenocarcinoma expressing PD-L1 has been superseded by SMC 2660. SMC advice relating to patients with carcinoma of the oesophagus expressing PD-L1 remains valid. Updates decision 17/05/22	16/08/2022

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2460</u>	In combination with chemotherapy, for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease. SMC restriction: for use in combination with paclitaxel or nab-paclitaxel. Treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2460 https://www.scottishmedicines.org.uk/media/7142/pembrol izumab-keytrudo-tnbc-final-september-2022-for-website.pdf Updates decision 18/10/22	21/02/2023
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2474</u>	In combination with lenvatinib, for the treatment of advanced or recurrent endometrial carcinoma in adults 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. <b>SMC restriction</b> : treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2474 https://www.scottishmedicines.org.uk/media/7140/pembrol izumab-keytruda-ec-final-sept-2022-amended-051022-for- website.pdf Updates decision 18/10/22	15/08/2023
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2479</u>	As monotherapy for the adjuvant treatment of adults with renal cell carcinoma (RCC) at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.	Routinely available in line with national guidance, SMC 2479 https://www.scottishmedicines.org.uk/media/7141/pembrol izumab-keytruda-rcc-final-sept-2022-for-website.pdf Updates decision 18/10/22	21/02/2023
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2501</u>	In combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS)≥1. <b>SMC restriction</b> : treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Routinely available in line with national guidance, SMC 2501 https://www.scottishmedicines.org.uk/media/7487/pembrol izumab-keytruda-final-jan-2023-amended-170123-for- website.pdf Updates decision 21/02/23	20/06/2023

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
pralsetinib 100mg hard capsules (Gavreto®)	2496	As monotherapy for the treatment of adult patients with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.	This medicine is now withdrawn from use/discontinued Updates decision 21/03/23	16/04/2024
remimazolam 20mg powder for solution for injection (Byfavo <sup>®</sup> )	<u>2454</u>	In adults for procedural sedation.	Not routinely available as not recommended for use in NHS Scotland, SMC 2454 https://www.scottishmedicines.org.uk/media/7040/remimaz olam-byfavo-final-july-2022-for-website.pdf	16/08/2022
risankizumab 150mg solution for injection in a prefilled syringe, pen (Skyrizi®)	<u>2459</u>	Alone or in combination with methotrexate (MTX), is indicated 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). <b>SMC restriction</b> : (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease- modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic- experienced population); and (iii) patients in whom TNF inhibitors are contraindicated or not tolerated.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	19/04/2022

**NHS Grampian decision** Date of decision **Condition being treated** Name Unique identifier roxadustat 20mg, 50mg, 70mg, 2461 Treatment of adult patients with symptomatic Routinely available in line with national guidance, 17/09/2024 100mg, 150mg film-coated tablets anaemia associated with chronic kidney disease SMC 2461 (Evrenzo<sup>®</sup>) (CKD). https://www.scottishmedicines.org.uk/media/7041/roxadust at-evrenzo-final-july-2022-for-website.pdf SMC restriction: for use in patients who are nondialysis dependent (NDD) at the time of treatment Updates decision 16/08/22 initiation. ruxolitinib 5mg, 10mg, 15mg, 20mg 2498 For the treatment of patients aged 12 years and Not routinely available as not recommended for use in NHS 21/06/2022 tablets (Jakavi®) older with: Scotland. - acute graft versus host disease who have SMC 2498 inadequate response to corticosteroids https://www.scottishmedicines.org.uk/media/6929/ruxolitini - chronic graft versus host disease who have b-jakavi-non-sub-final-may-2022-for-website.pdf inadequate response to corticosteroids Ryeqo<sup>®</sup> 40mg/1mg/0.5mg film-Treatment of moderate to severe symptoms of Routinely available in line with national guidance, 20/12/2022 2442 coated tablets (relugolix/ estradiol/ uterine fibroids in adult women of reproductive SMC 2442 https://www.scottishmedicines.org.uk/media/6928/relugolixnorethisterone acetate) age. **SMC restriction**: for use in patients who have estradiol-norethisterone-acetate-ryego-final-may-2022-forfailed or are unsuitable for conventional therapies website.pdf (first line treatments), such as tranexamic acid, Updates decision 21/06/22 hormonal contraceptives and intrauterine delivery systems. Sativex<sup>®</sup> Oromucosal Spray 2473 As treatment for symptom improvement in adult Routinely available in line with national guidance, 21/02/2023 2.7mg/2.5mg per 100microlitre spray patients with moderate to severe spasticity due to SMC 2473 (delta-9-tetrahydrocannabinol multiple sclerosis (MS) who have not responded https://www.scottishmedicines.org.uk/media/7097/delta-9tetrahydrocannabinod-sativex-final-aug-2022-for-/cannabidiol) adequately to other anti-spasticity medication and who demonstrate clinically significant website.pdf improvement in spasticity related symptoms Updates decision 20/09/22 during an initial trial of therapy.

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
setmelanotide 10mg/mL solution for injection (Imcivree®)	<u>2565</u>	Treatment of obesity and the control of hunger associated with genetically confirmed loss-of- function biallelic pro-opiomelanocortin (POMC), including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 6 years of age and above.	Not routinely available as not recommended for use in NHS Scotland, SMC 2565 https://www.scottishmedicines.org.uk/media/7358/setmela notide-imcivree-non-sub-final-dec-2022-for-website.pdf	17/01/2023
Sibnayal <sup>®</sup> 8mEq/24mEq prolonged- release granules (potassium citrate/potassium hydrogen carbonate)	<u>2409</u>	For the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	16/08/2022
sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®)	<u>2515</u>	In the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care. <b>Restriction:</b> correction phase use, within the renal department/at the request of renal physicians, as emergency bridging use for adults where dialysis is unavailable but urgently needed and potassium is dangerously elevated.	Routinely available in line with local guidance	15/11/2022
solriamfetol 75mg, 150mg film- coated tablets (Sunosi®)	<u>2439</u>	To improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy). <b>SMC restriction</b> : for use in patients who have failed modafinil or have a contraindication or intolerance to modafinil.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time Updates decision 16/08/22	20/09/2022
somatrogon 24mg, 60mg solution for injection in pre-filled pen (Ngenla <sup>®</sup> )	<u>2493</u>	For the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone.	Routinely available in line with national guidance, SMC 2493 https://www.scottishmedicines.org.uk/media/7042/somatro gon-ngenla-abb-final-july-2022-for-website.pdf Updates decision 16/08/22	21/02/2023

**NHS Grampian decision** Date of decision **Condition being treated** Name Unique identifier sotrovimab 500mg concentrate for 2555 Treatment of symptomatic adults and adolescents Not routinely available as local clinical experts do not wish to 20/06/2023 solution for infusion (Xevudy<sup>®</sup>) (aged 12 years and over and weighing at least add the medicine to the formulary at this time, 40kg) with acute COVID-19 infection who do not Updates decision 18/04/23 require oxygen supplementation and who are at increased risk of progressing to severe COVID infection. SMC restriction: patients with increased risk for progression to severe COVID-19, as defined in the independent advisory group report commissioned by the Department of Health and nirmatrelvir and ritonavir is contraindicated or unsuitable. tepotinib 225mg film-coated tablets 2535 For the treatment of adult patients with advanced Routinely available in line with national guidance, 18/02/2025 (Tepmetko<sup>®</sup>) non-small cell lung cancer (NSCLC) harbouring SMC 2535 mesenchymal-epithelial transition factor gene https://scottishmedicines.org.uk/media/7359/tepotinibtepmekto-resub-final-dec-2022-updated-211222docxfor-(MET) exon 14 (METex14) skipping alterations. website.pdf Updates decision 17/01/23 tisagenlecleucel  $1.2 \times 10^6 - 6 \times 10^8$ 17/01/2023 Treatment of adult patients with relapsed or Not routinely available as not recommended for use in NHS 2566 refractory follicular lymphoma after two or more Scotland, cells dispersion for infusion 2566 lines of systemic therapy. (Kymriah<sup>®</sup>) https://www.scottishmedicines.org.uk/media/7360/tisagenl ecleucel-kymriah-non-sub-final-dec-2022-for-website.pdf tocilizumab 20mg/mL concentrate for 2552 Treatment of COVID-19 in adults who are Routinely available in line with national guidance, 20/06/2023 NICE TA878 solution for infusion (RoActemra<sup>®</sup>) receiving systemic corticosteroids and require https://www.nice.org.uk/guidance/ta878 supplemental oxygen or mechanical ventilation. Updates decision 18/04/23 tofacitinib 5mg film-coated tablets 2463 For the treatment of adult patients with active Routinely available in line with national guidance, 16/05/2023 ankylosing spondylitis (AS) who have responded SMC 2463 (Xeljanz<sup>®</sup>) https://www.scottishmedicines.org.uk/media/7092/tofacitini inadequately to conventional therapy. b-xeljanz-final-aug-2022-amended-070922-for-website.pdf Updates decision 20/09/22

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
trifarotene 50microgram/g cream (Aklief®)	<u>2441</u>	For the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.	Routinely available in line with national guidance, SMC 2441 https://www.scottishmedicines.org.uk/media/7093/trifarote ne-aklief-abbreviated-final-jan-2022-amended-130722-for- website.pdf Updates decision 20/09/22	20/02/2024
Trimbow <sup>®</sup> 172micrograms/ 5micrograms/9micrograms pressurised inhalation solution (beclometasone dipropionate/ formoterol fumarate dihydrate/ glycopyrronium)	<u>2334</u>	Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.	Routinely available in line with local guidance, Updates decision 16/08/22	18/10/2022
upadacitinib 15mg prolonged-release tablets (Rinvoq®)	<u>2480</u>	For the treatment of active ankylosing spondylitis (AS) in adult patients who have responded inadequately to conventional therapy.	Routinely available in line with national guidance, SMC 2480 https://www.scottishmedicines.org.uk/media/7209/upadacit inib-rinvoq-final-oct-2022docxfor-website.pdf Updates decision 15/11/22	16/05/2023
upadacitinib 15mg prolonged-release tablets (Rinvoq®)	2 <u>495</u>	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. <b>SMC restriction:</b> in adults with moderate disease (a disease activity score [DAS28] of 3.2 to 5.1) when intensive therapy with 2 or more conventional DMARDs has not controlled the disease well enough.	Routinely available in line with national guidance, SMC 2495 https://www.scottishmedicines.org.uk/media/7295/upadacit inib-rinvoq-resub-final-nov-2022-amended-081222-for- website.pdf Updates decision 20/12/22	16/05/2023

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
upadacitinib 15mg prolonged-release tablets (Rinvoq®)	<u>2532</u>	For the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C- reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).	Routinely available in line with national guidance, SMC 2532 https://www.scottishmedicines.org.uk/media/7407/upadaci nib-rinvoq-nr-axspa-abb-final-jan-2023-for-website.pdf Updates decision 21/02/23	16/05/2023
upadacitinib 15mg, 30mg prolonged- release tablets (Rinvoq®)	<u>2417</u>	For the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. <b>SMC restriction:</b> patients who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.	Routinely available in line with national guidance, SMC 2417 https://www.scottishmedicines.org.uk/media/6797/upadacit inib-rinvoq-final-march-2022-for-website.pdf Updates decision 19/04/22	20/09/2022
upadacitinib 15mg, 30mg, 45mg prolonged-release tablets (Rinvoq®)	<u>2510</u>	For the treatment of adult patients 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.	Routinely available in line with national guidance, SMC 2510 https://www.scottishmedicines.org.uk/media/7143/upadacit inib-rinvoq-uc-abb-final-sept-2022-for-website.pdf Updates decision 18/10/22	16/05/2023
vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®)	<u>2506</u>	Treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2506 https://www.scottishmedicines.org.uk/media/6987/vedolizu mab-entyvio-non-sub-final-june-2022-for-website.pdf	16/08/2022
venetoclax 10mg, 50mg, 100mg film- coated tablets (Venclyxto®)	<u>2412</u>	In combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.	Routinely available in line with national guidance, SMC 2412 https://www.scottishmedicines.org.uk/media/6803/venetocl ax-venclyxto-final-march-2022-for-website-amended- 110422.pdf Updates decision 19/04/22	18/10/2022

Date of decision **Condition being treated NHS Grampian decision** Name Unique identifier venetoclax 10mg, 50mg, 100mg film-2427 In combination with obinutuzumab for the Routinely available in line with national guidance, 20/09/2022 coated tablets (Venclyxto®) treatment of adult patients with previously SMC 2427 untreated chronic lymphocytic leukaemia (CLL). https://www.scottishmedicines.org.uk/media/6859/venetocl ax-venclyxto-final-april-2022-for-website.pdf SMC restriction: in patients without del Updates decision 17/05/22 (17p)/TP53 mutation who are fit to receive fludarabine, cyclophosphamide and rituximab (FCR) chemo-immunotherapy. venetoclax 10mg, 50mg, 100mg film-2509 In combination with low-dose cytarabine for the Not routinely available as not recommended for use in NHS 15/11/2022 coated tablets (Venclyxto®) treatment of adult patients with newly-diagnosed Scotland, acute myeloid leukaemia (AML) who are ineligible SMC 2509 https://www.scottishmedicines.org.uk/media/7210/venetocl for intensive chemotherapy. ax-venclyxto-non-sub-final-oct-2022docxfor-website.pdf As monotherapy for the treatment of adult zanubrutinib 80mg hard capsules Routinely available in line with national guidance, 18/04/2023 2528 patients with Waldenström's macroglobulinaemia SMC 2528 (Brukinsa<sup>®</sup>) https://www.scottishmedicines.org.uk/media/7211/zanubru (WM) who have received at least one prior tinib-brukinsa-resub-final-oct-2022docxfor-website.pdf therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. Updates decision 15/11/22 Zubsolv<sup>®</sup> 1.4mg/0.36mg, 2123 Substitution treatment for opioid drug Not routinely available as there is a local preference for 15/11/2022 2.9mg/0.71mg, 5.7mg/1.4mg, dependence, within a framework of medical, alternative medicines 8.6mg/2.1mg, 11.4mg/2.9mg social and psychological treatment. The intention sublingual tablets of the naloxone component is to deter (buprenorphine/naloxone) intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. SMC restriction: for use in patients for whom methadone is not suitable.