#### **NHS GRAMPIAN NEW MEDICINES DECISIONS**

In Scotland, a newly licensed medicine is routinely available in a health board only after it has been:

- accepted for use in NHS Scotland by the Scottish Medicines Consortium (SMC), and
- accepted for use by the health board's Area Drug and Therapeutics Committee (ADTC).

All medicines accepted by SMC are available in Scotland, but may not be considered 'routinely available' within a particular health board because of available services and preferences for alternative medicines.

'Routinely available' means that a medicine can be prescribed by the appropriately qualified person within a health board.

Each health board has an ADTC. The ADTC, Grampian Area Drug and Therapeutics Committee, is responsible for advising NHS Grampian health board on all aspects of the use of medicines.

Medicines routinely available within NHS Grampian are usually included in the Grampian Joint Formulary. The formulary is a list of medicines for use in the health board that has been agreed by the ADTC in consultation with local clinical experts. It offers a choice of medicines for healthcare professionals to prescribe for common medical conditions. A formulary can help improve safety as prescribers are likely to become more familiar with the medicines in it and also helps make sure that standards of care are consistent across the health board.

# How does the health board decide which new medicines to make routinely available for patients?

The ADTC in a health board will consider national and local guidance before deciding whether to make a new medicine routinely available.

### What national guidance does the ADTC consider?

- SMC advice: The SMC considers newly licensed medicines and advises health boards in Scotland whether they should be available. When SMC considers a new medicine for the NHS in Scotland, it looks at:
  - how well the medicine works,
  - which patients might benefit from it,
  - whether it is as good or better than medicines the NHS already uses to treat the medical condition, and
  - whether it is good value for money.
- In the table below, national guidance usually refers to SMC advice. Links to SMC advice for individual medicines are also included in the table.
- In some cases, other agencies may also provide guidance on how medicines should be used. For example, Healthcare Improvement Scotland issues alerts to advise if National Institute for Health and Care Excellence Multiple Technology Appraisals (NICE MTAs) are applicable in Scotland.

# What local guidance does the ADTC consider?

 Advice from local clinical experts who would be expected to prescribe a particular medicine, where that service is available in a health board.

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# Why is a particular medicine not routinely available in NHS Grampian?

- This is usually because the medicine is not recommended for use in NHS Scotland by the SMC.
- The medicine may not be routinely available in a health board, particularly in smaller health boards, because there is not a suitable specialist who may use the medicine.
- There may also be differences as to which medicines are preferred in health boards. Sometimes SMC accepts more than one medicine for treating a specific medical condition. Clinical experts in each health board consider whether to add new medicines to their formulary and advise the ADTC. Sometimes it is agreed that established medicines are a better choice than new medicines.

# What happens if a particular medicine is not routinely available in NHS Grampian?

If a medicine is not routinely available and not included in the Grampian Joint Formulary and there are no suitable alternatives on the formulary, a healthcare professional can request to prescribe a medicine that is not on the formulary if they think you will benefit from using it. All health boards have procedures in place to consider requests when a healthcare professional feels a medicine that is not on the formulary would be right for a particular patient.

The table below lists NHS Grampian's latest decisions on medicines.

If you need more information on medicines decisions in NHS Grampian, please email gram.formularyteam@nhs.scot.

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This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
anakinra 100mg solution for injection in prefilled syringe (Kineret®)		[Off-label use] For the treatment of adults with: - chimeric antigen receptor (CAR) T cell-induced severe or life-threatening grade 4 cytokine release syndrome (CRS) with no improvement after dexamethasone - grade 3 or 4 Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) where steroid response is suboptimal or ICANS worsens on tapering of steroids	Routinely available in line with local guidance	20/08/2024
axicabtagene ciloleucel 0.4 – 2 x 10^8 cells dispersion for infusion (Yescarta®)	<u>2189</u>	Treatment of adults with relapsed or refractory diffuse large B cell lymphoma (DLBCL) and primary mediastinal large B cell lymphoma (PMBCL), after two or more lines of systemic therapy.	Routinely available in line with national guidance, SMC 2189 https://scottishmedicines.org.uk/media/8485/axicabtagene- ciloleucel-yescarta-resub-final-sept-2019-amended-180724- for-website.pdf	20/08/2024
birch bark extract 23.4mg gel (Filsuvez®)	<u>2651</u>	For treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients aged 6 months and older.	Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).	20/08/2024
brexucabtagene autoleucel 0.4 – 2 × 10^8 cells dispersion for infusion (Tecartus®)	<u>2351</u>	For the treatment of adults with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.	Routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment, SMC 2351 https://www.scottishmedicines.org.uk/media/6180/autologo us-tecartus-final-july-2021-for-website.pdf	20/08/2024
brexucabtagene autoleucel $0.4 - 2 \times 10^{8}$ cells dispersion for infusion (Tecartus®)	<u>2548</u>	Treatment of adults 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).	Routinely available in line with national guidance, SMC 2548 https://scottishmedicines.org.uk/media/7869/brexucabtage ne-autoleucel-tecartus-final-sept-2023-for-website.pdf	20/08/2024
daratumumab 1,800mg solution for subcutaneous injection, 20mg/mL concentrate for solution for infusion (Darzalex®)	467/24	[Off-label use] In combination with bortezomib, lenalidomide and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.	Routinely available in line with local guidance	20/08/2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
dasatinib 20mg, 50mg, 80mg, 100mg, 140mg film-coated tablets	<u>116</u>	[Off-label use] for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) integrated with chemotherapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
dasatinib 20mg, 50mg, 80mg, 100mg, 140mg film-coated tablets	<u>117</u>	For the treatment of adult patients with Philadelphia chromosome–positive (Ph+) acute lymphoblastic leukaemia with resistance or intolerance to prior therapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
empagliflozin 10mg, 25mg film-coated tablets (Jardiance®)	2642	In adults for the treatment of chronic kidney disease.  SMC restriction: in patients having individually optimised standard care (including angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment:  • an estimated glomerular filtration rate (eGFR) of 20mL/min/1.73m² up to 45mL/min/1.73m², or  • an eGFR of 45mL/min/1.73m² up to 90mL/min/1.73m² and either:  o A urine albumin-to-creatinine ratio (uACR) of 22.6mg/mmol or more, or o Type 2 Diabetes Mellitus (T2DM)	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
etranacogene dezaparvovec 1 x 10^13 genome copies/mL concentrate for solution for infusion (Hemgenix®)	<u>2649</u>	For the treatment of severe and moderately severe haemophilia B (congenital factor IX deficiency) in adult patients without a history of factor IX inhibitors.	Routinely available from a specialist centre in another health board	20/08/2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
fezolinetant 45mg film-coated tablets (Veoza®)	<u>2702</u>	Treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.	Not routinely available as not recommended for use in NHS Scotland, SMC 2702 https://scottishmedicines.org.uk/media/8525/fezolinetant-veoza-non-sub-final-july-2024-for-website.pdf	20/08/2024
follitropin delta 12micrograms/0.36mL, 36micrograms/1.08mL, 72micrograms/2.16mL solution for injection in a pre-filled pen (Rekovelle®)	<u>2670</u>	Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle.  SMC restriction: for use in normal responders (patients with an anti-Müllerian hormone level of >5.4 pmol/L) or high responders (patients with an anti-Müllerian hormone level of ≥25 pmol/L).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
Kaftrio® 37.5mg/25mg/50mg, 75mg/50mg/100mg film coated tablets, 60mg/40mg/80mg, 75mg/50mg/100mg granules (elexacaftor/ivacaftor/tezacaftor)	<u>2713</u>	In a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 2 years to less than 6 years (granules in sachet) and 6 years and older (film-coated tablets) who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024

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NHS Grampian New Medicines Decisions – Formulary Group decisions 20 August 2024

Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
lenacapavir 300mg film-coated tablets, 464mg solution for injection (Sunlenca®)	<u>2691</u>	Film-coated tablets: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection.  Solution for injection: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.	Not routinely available as not recommended for use in NHS Scotland, SMC 2691 https://www.scottishmedicines.org.uk/media/8457/lenacap avir-sunlenca-non-sub-final-june-2024-for-website.pdf	20/08/2024
levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Benilexa® One Handed)		Contraception (as licensed for 6 years).	Routinely available in line with local guidance	20/08/2024
levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Benilexa® One Handed)		[Off-label use] As contraception: - for up to 8 years if the user is under 45 years at time of insertion until the age of 55 years if the user is over the age of 45 years at the time of insertion.	Routinely available in line with national guidance, The Faculty of Sexual & Reproductive Healthcare (FSRH) https://www.fsrh.org/Common/Uploaded%20files/documen ts/fsrh-ceu-statement-extended-use-of-all-52mg-lng-iuds-for- up-to-eight-years-for-contraception.pdf	20/08/2024
levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Levosert®)		Contraception for 8 years (licence extension).	Routinely available in line with local guidance	20/08/2024
levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Mirena®)		Contraception for 8 years (licence extension).	Routinely available in line with local guidance	20/08/2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
Lonsurf® 15mg/6.14mg, 20mg/8.19mg film-coated tablets (trifluridine/tipiracil)	<u>2654</u>	In combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer (CRC) who have received two prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecanbased chemotherapies, anti-VEGF agents, and/or anti-EGFR agents.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
mirikizumab 100mg solution for injection in pre-filled pen, 300mg concentrate for solution for infusion (Omvoh®)	<u>2650</u>	For the treatment of adults 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 treatment.  Restriction: for adults who have had an inadequate response with, lost response to, or were intolerant to biologic treatment.	Routinely available in line with local guidance	20/08/2024
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	<u>2704</u>	Adjuvant treatment of adults and adolescents 12 years of age and older with Stage IIB or IIC melanoma.	Not routinely available as not recommended for use in NHS Scotland, SMC 2704 https://scottishmedicines.org.uk/media/8520/nivolumab- opdivo-non-sub-final-july-2024-for-website.pdf	20/08/2024
Opdualag® 240mg/80mg concentrate for solution for infusion (nivolumab/relatlimab)	<u>2645</u>	First-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
Orkambi® 100mg/125mg, 200mg/125mg film-coated tablets, 75mg /94mg, 100mg/125mg, 150mg/188mg granules in sachets (lumacaftor/ivacaftor)	<u>2712</u>	The treatment of cystic fibrosis (CF) in patients aged 1 year and older (granules in sachet) or 6 years and older (film-coated tablets) who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
pegunigalsidase alfa 2mg/mL concentrate for solution for infusion (Elfabrio®)	<u>2665</u>	For long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase).  SMC restriction: for use in adults with symptomatic Fabry disease who would usually be offered an enzyme replacement therapy.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2644</u>	In combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1.	Not routinely available as not recommended for use in NHS Scotland, SMC 2644 https://www.scottishmedicines.org.uk/media/8460/pembrolizumab-keytruda-mgc-final-june-2024-for-website.pdf	20/08/2024
pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)	<u>2660</u>	In combination with fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death-ligand 1 (PD-L1) with a combined positive score (CPS) ≥ 1.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024
remimazolam 50mg powder for concentrate for solution for injection/infusion (Byfavo®)	<u>2692</u>	In adults for intravenous induction and maintenance of general anaesthesia.	Not routinely available as not recommended for use in NHS Scotland, SMC 2692 https://www.scottishmedicines.org.uk/media/8462/remimaz olam-byfavo-non-sub-final-june-2024-for-website.pdf	20/08/2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
siltuximab 100mg, 400mg powder for concentrate for solution for infusion (Sylvant®)		[Off-label use] For the treatment of adults with: - chimeric antigen receptor (CAR) T cell-induced severe or life-threatening grade 4 cytokine release syndrome (CRS) in refractory cases - grade 3 or 4 Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) despite high dose steroids and anakinra	Routinely available in line with local guidance	20/08/2024
sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®)	<u>2288</u>	For the treatment of hyperkalaemia in adults.  Restriction: chronic use [maintenance phase] for adults with persistent/recurrent hyperkalaemia and heart failure, with or without chronic kidney disease stage 3b to 5 if they:  - have a confirmed serum potassium level of at least 6.0mmol/litre and  - are not taking an optimised dosage of reninangiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia  - stop sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable	Routinely available in line with local guidance.  Treatment must be initiated and supervised by specialist physicians in the Heart Failure/Cardiologist department.	20/08/2024
Symkevi® 50mg/75mg, 100mg/150mg film-coated tablets (tezacaftor/ivacaftor)	<u>2711</u>	In a combination regimen with ivacaftor tablets for the treatment of patients with cystic fibrosis (CF) aged 6 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	20/08/2024

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
talquetamab 2mg/mL, 40mg/mL solution for injection (Talvey®)	<u>2705</u>	As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2705 https://scottishmedicines.org.uk/media/8521/talquetamabtalvey-non-sub-final-july-2024-for-website.pdf	20/08/2024
tocilizumab 20mg/mL concentrate for solution for infusion (Tyenne®)		For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults.	Routinely available in line with local guidance	20/08/2024
trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®)	<u>2693</u>	As monotherapy for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.	Not routinely available as not recommended for use in NHS Scotland, SMC 2693 https://www.scottishmedicines.org.uk/media/8463/trastuzu mab-deruxtecan-enhertu-non-sub-final-june-2024-forwebsite.pdf	20/08/2024
trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®)	2706	As monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy.	Not routinely available as not recommended for use in NHS Scotland, SMC 2706 https://scottishmedicines.org.uk/media/8522/trastuzumab-deruxtecan-enhertu-non-sub-final-july-2024-amended-070824-for-website.pdf	20/08/2024
voretigene neparvovec 5 x 10^12 vector genomes/mL concentrate and solvent for solution for injection (Luxturna®)	<u>2641</u>	For the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.	Routinely available from a specialist centre in another health board	20/08/2024
Xonvea® 10mg/10mg gastro-resistant tablets (doxylamine succinate/pyridoxine hydrochloride)	450/22	For the treatment of severe nausea and vomiting in pregnancy (NVP) and Hyperemesis gravidarum (HG).	Routinely available in line with local guidance	20/08/2024

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