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
atezolizumab 1,875mg solution for injection (Tecentriq®)		In line with the current formulary acceptance for the intravenous infusion, including any restrictions.	Routinely available in line with local guidance	21/11/2023
atogepant 10mg, 60mg tablets (Aquipta®)	<u>2599</u>	For the prevention of migraine in adults with: 1) chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine) whose condition has failed to respond to three or more prior oral prophylactic treatments 2) high frequency episodic migraine (headaches on 10 - 14 days per month) whose condition has failed to respond to three or more prior oral prophylactic treatments	Routinely available in line with local guidance	21/11/2023
avacopan 10mg hard capsules (Tavneos®)	<u>2578</u>	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).	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023
bimekizumab 160mg solution for injection in pre-filled syringe, pre-filled pen (Bimzelx®)	<u>2605</u>	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.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023
cerliponase alfa 150mg solution for infusion (Brineura®)	<u>2286</u>	For the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.	Not routinely available in NHS Grampian. If local need identified treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme.	21/11/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
dabrafenib 50mg, 75mg hard capsules (Tafinlar®) plus trametinib 0.5mg, 2mg film-coated tablets (Mekinist®)	<u>107</u>	[Off-label use] Treatment of patients with locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation and with no satisfactory locoregional treatment options.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023
durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®)	<u>2582</u>	In combination with gemcitabine and cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023
efgartigimod alfa 20mg/mL concentrate for solution for infusion (Vyvgart®)	<u>2561</u>	As an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are antiacetylcholine receptor (AChR) antibody positive.	Not routinely available as not recommended for use in NHS Scotland, SMC 2561 https://www.scottishmedicines.org.uk/media/7931/efgartigi mod-alfa-vyvgart-final-oct-2023-amended-251023-forwebsite.pdf	21/11/2023
eletriptan 20mg, 40mg film-coated tablets		In adults for the acute treatment of the headache phase of migraine attacks, with or without aura. Restriction: third-line oral triptan.	Routinely available in line with local guidance	21/11/2023
erenumab 70mg, 140mg solution for injection in prefilled pen (Aimovig®)		For the prevention of migraine in adults with high frequency episodic migraine (headaches on 10 - 14 days per month) whose condition has failed to respond to three or more prior oral prophylactic treatments.	Routinely available in line with local guidance	21/11/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
fidaxomicin 200mg film-coated tablets		For the treatment of <i>Clostridioides difficile</i> infections (CDI) also known as <i>C. difficile</i> - associated diarrhoea (CDAD) in adult and paediatric patients with a body weight of at least 12.5kg. Consideration should be given to official guidelines on the appropriate use of antibacterial agents. Restriction: in line with the antibiotic treatment recommendations of NICE guideline NG199, July 2021. Treatment should be started by, or after advice from a Medical Microbiologist or Infection Specialist.	Routinely available in line with national guidance, NG199 https://www.nice.org.uk/guidance/ng199	21/11/2023
fidaxomicin 40mg/mL granules for oral suspension		For the treatment of <i>Clostridioides difficile</i> infections (CDI) also known as <i>C. difficile</i> - associated diarrhoea (CDAD) in adults and paediatric patients from birth to < 18 years of age. Consideration should be given to official guidelines on the appropriate use of antibacterial agents. Restriction: in line with antibiotic treatment recommendations of NICE guideline NG199, July 2021. Treatment should be started by, or after advice from a Medical Microbiologist or Infection Specialist	Routinely available in line with national guidance, NG199 https://www.nice.org.uk/guidance/ng199	21/11/2023
ibrutinib 140mg, 280mg, 420mg film- coated tablets (Imbruvica®)	<u>2543</u>	In combination with venetoclax for the treatment of adults 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	21/11/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
lanreotide Ipsen 60mg, 90mg, 120mg solution for injection (previously Somatuline® Autogel®)		In line with the current formulary acceptance, including any restrictions.	Routinely available in line with local guidance	21/11/2023
mercaptamine 25mg, 75mg gastro- resistant hard capsules (Procysbi®)	<u>2571</u>	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/mercapt amine-procysbi-resub-final-oct-2023-amended-031123-for-website.pdf	21/11/2023
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)	<u>106</u>	[Off-label use] Treatment of patients with pleural or peritoneal mesothelioma; second or subsequent line.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023
pegunigalsidase alfa 2mg/mL concentrate for solution for infusion (Elfabrio®)	<u>2591</u>	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/pegunig alsidase-alfa-elfabrio-final-oct-2023-amended-111023-261023-for-website.pdf	21/11/2023
progesterone 200mg vaginal capsules (Utrogestan®)	<u>2630</u>	Prevention of preterm birth in women with a singleton pregnancy who have a short cervix (midtrimester 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/progeste rone-vaginal-capsules-utrogestan-non-sub-final-oct-2023-forwebsite.pdf	21/11/2023
rimegepant 75mg oral lyophilisate (Vydura®)	<u>2603</u>	For the prevention of migraine in adults with high frequency episodic migraine (headaches on 10 - 14 days per month) whose condition has failed to respond to three or more prior oral prophylactic treatments.	Routinely available in line with local guidance	21/11/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
risankizumab 600mg concentrate for solution for infusion, 360mg solution for injection (Skyrizi®)	<u>2534</u>	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.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	21/11/2023
selpercatinib 40mg, 80mg hard capsules (Retsevmo®)	<u>2573</u>	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
sumatriptan 3mg/0.5mL solution for injection in pre-filled pen		In adults for the acute relief of migraine attacks, with or without aura. Sumatriptan should only be used where there is a clear diagnosis of migraine.	Routinely available in line with local guidance	21/11/2023
tafamidis 61mg soft capsules (Vyndaqel®)	<u>2585</u>	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
tobramycin 1.2g powder [unlicensed]	458/23	[unlicensed product] For local antibiotic treatment of patients with infected non-union or high-risk of infection fractures to coat intramedullary nail with antibiotic loaded calcium sulfate.	Routinely available in line with local guidance	21/11/2023
voclosporin 7.9mg soft capsule (Lupkynis®)	<u>2570</u>	In combination with mycophenolate mofetil for the treatment of adults 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	21/11/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
vutrisiran 25mg solution for injection in prefilled syringe (Amvuttra®)	<u>2596</u>	For the treatment of hereditary transthyretinmediated amyloidosis (hATTR amyloidosis) in adults with stage 1 or stage 2 polyneuropathy.	Routinely available in line with national guidance, SMC 2596 https://www.scottishmedicines.org.uk/media/7824/vutrisira n-amvuttra-abb-final-aug-2023-for-website-amended- 2508.pdf	21/11/2023
zanubrutinib 80mg hard capsules (Brukinsa®)	<u>2600</u>	As monotherapy for the treatment of adults with chronic lymphocytic leukaemia (CLL) in whom chemo-immunotherapy is unsuitable.	Routinely available in line with national guidance, SMC 2600 https://www.scottishmedicines.org.uk/media/7866/zanubru tinib-brukinsa-abb-final-sept-2023-for-website.pdf	21/11/2023
zolmitriptan 2.5mg, 5mg tablets, orodispersible tablets		In adults for the acute treatment of migraine headache with or without aura.	Not routinely available as there is a local preference for alternative medicines	21/11/2023

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