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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NHS Grampian New Medicines Decisions - Formulary Group decisions 15 August 2023

Name	Unique	Condition being treated	NHS Grampian decision	Date of decision
	identifier			
abiraterone acetate 500mg film- coated tablets	<u>110</u>	[Off-label use] In combination with prednisolone and androgen deprivation therapy for the treatment of newly diagnosed low-risk metastatic hormone-sensitive prostate cancer patients who are not suitable for currently accessible on-label alternatives.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/08/2023
Acarizax 12 SQ-HDM oral lyophilisate (Dermatophagoides pteronyssinus and Dermatophagoides farinae)	s <u>2613</u>	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: - 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 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.	Not routinely available as not recommended for use in NHS Scotland, SMC 2613 https://www.scottishmedicines.org.uk/media/7752/dermato phagoides-acarizax-non-sub-final-july-2023-for-website.pdf	15/08/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
adefovir dipivoxil 10mg tablets (Hepsera®)		In adults for the treatment of chronic hepatitis B with: - compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and fibrosis. Initiation of Hepsera® treatment should only be considered when the use of an alternative antiviral agent with a higher genetic barrier to resistance is not available or appropriate - decompensated liver disease in combination with a second agent without cross-resistance to Hepsera®	This medicine is now withdrawn from use/discontinued	15/08/2023
aflibercept 40mg/mL solution for injection in pre-filled syringe (Eylea®)	<u>2612</u>	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.	Not routinely available as not recommended for use in NHS Scotland, SMC 2612 https://www.scottishmedicines.org.uk/media/7755/afliberce pt-eylea-non-sub-final-july-2023-for-website.pdf	15/08/2023
apalutamide 60mg film-coated tablets (Erleada®)	<u>2579</u>	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
avalglucosidase alfa 100mg powder for concentrate for solution for infusion (Nexviadyme®)	<u>2546</u>	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/avalgluc osidase-alfa-nexviadyme-abb-final-june-2023-for-website.pdf	15/08/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
azacitidine 200mg, 300mg film- coated tablets (Onureg®)	<u>2533</u>	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/azacitidi ne-onureg-final-june-2023-updated-270623-for-website.pdf	15/08/2023
azacitidine 25mg/mL powder for suspension for injection		As monotherapy for the treatment of adults who are not eligible for haematopoietic stem cell transplantation (HSCT) with acute myeloid leukaemia (AML).	Not routinely available as there is a local preference for alternative medicines	15/08/2023
baricitinib 2mg, 4mg film-coated tablets (Olumiant®)	<u>2572</u>	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/baricitini b-olumiant-final-july-2023-for-website.pdf	15/08/2023
belumosudil 200mg film-coated tablet (Rezurock®)	<u>2583</u>	Treatment of patients aged 12 years and older with chronic graft-versus-host disease (chronic GvHD) who have received at least two prior lines of systemic therapy.	Not routinely available in NHS Grampian. If local need identified, treatment is available through the National Services Scotland Ultra-orphan medicines Risk Share Scheme.	15/08/2023
brigatinib 30mg, 90mg, 180mg film-coated tablets (Alunbrig®)	<u>2314</u>	As monotherapy for the treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.	Routinely available in line with national guidance, SMC 2314 https://www.scottishmedicines.org.uk/media/5706/brigatinib-alumbrig-final-dec-2020docx-for-website.pdf	15/08/2023
casirivimab 120mg/mL plus imdevimab 120mg/mL solution for injection or infusion (Ronapreve®)	2553	Treatment of acute COVID-19 infection.	This medicine is now withdrawn from use/discontinued	15/08/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®)	<u>2577</u>	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/dapaglifl ozin-forxiga-abb-final-july-2023-for-website.pdf	15/08/2023
dexamethasone 500microgram, 2mg tablets, 2mg soluble tablets, 2mg/5mL oral solution, 3.3mg/mL solution for injection		For the treatment of COVID-19 in people who: - need supplemental oxygen to meet their prescribed oxygen saturation levels or - have a level of hypoxia that needs supplemental oxygen but who are unable to have or tolerate it	Routinely available in line with national guidance, COVID-19 rapid guideline: Managing COVID-19 https://app.magicapp.org/#/guideline/L4Qb5n/section/n3e9 gj	15/08/2023
empagliflozin 10mg film-coated table (Jardiance®)	t <u>2523</u>	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	15/08/2023
fluticasone propionate 400microgram/unit dose nasal drops		For the regular treatment of nasal polyps and associated symptoms of nasal obstruction.	Routinely available in line with local guidance	15/08/2023
fluticasone propionate 400microgram/unit dose nasal drops (Flixonase® Nasule®)		For the regular treatment of nasal polyps and associated symptoms of nasal obstruction.	This medicine is now withdrawn from use/discontinued	15/08/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
GoResp® Digihaler®		For the treatment of adults 18 years of age and	Not routinely available in NHS Grampian	15/08/2023
160micrograms/4.5micrograms,		older only.		
320micrograms/9micrograms		Asthma - In the regular treatment of asthma,		
budesonide / formoterol fumarate		where use of a combination (inhaled		
dihydrate		corticosteroid and long-acting β2 adrenoceptor		
		agonist) is appropriate:		
		- in patients not adequately controlled with		
		inhaled corticosteroids and "as needed" inhaled		
		short-acting β2 adrenoceptor agonists, OR		
		- in patients already adequately controlled on		
		both inhaled corticosteroids and long-acting $\beta 2$		
		adrenoceptor agonists.		
		COPD - Symptomatic treatment of patients with		
		COPD with forced expiratory volume in 1 second		
		(FEV1) < 70% predicted normal (post		
		bronchodilator) and a history of repeated		
		exacerbations, who have significant symptoms		
		despite regular therapy with long-acting		
		bronchodilators.		

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
icosapent ethyl 998mg soft capsules (Vazkepa®)	2602	To reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (≥1.7mmol/L) and - established cardiovascular disease, or - diabetes, and at least one other cardiovascular risk factor. 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: - 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
lenvatinib 4mg, 10mg hard capsules (Lenvima®)		In combination with pembrolizumab, 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.	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-forwebsite.pdf	15/08/2023
lorlatinib 25mg, 100mg film-coated tablets (Lorviqua®)	<u>2415</u>	As monotherapy for the treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.	Not routinely available as there is a local preference for alternative medicines	15/08/2023

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Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
	For the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents aged from 3 months to less than 18 years.	Routinely available in line with local guidance	15/08/2023
TA11297	Adults with COVID-19 who: - do not need supplemental oxygen for COVID-19, and - are within 5 days of symptom onset, and - are thought to be at high risk of progression to severe COVID-19	Routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment, TA11297 https://www.nice.org.uk/guidance/indevelopment/gidta11297	15/08/2023
<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. Restriction: 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	15/08/2023
<u>2538</u>	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/pembrol izumab-keytruda-final-may-2023-for-website.pdf	15/08/2023
<u>109</u>	[Off-label use] In combination with cisplatin as adjuvant treatment for patients with completely resected stage IIA to IIIA non-squamous, non-small-cell lung cancer.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/08/2023
<u>2524</u>	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).	Routinely available in line with national guidance, SMC 2524 https://www.scottishmedicines.org.uk/media/7703/polatuzu mab-vedotin-polivy-reasessment-final-june-2023-for- website.pdf	15/08/2023
	Unique identifier TA11297 2474 2538	For the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents aged from 3 months to less than 18 years. TA11297 Adults with COVID-19 who:	Talley For the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents aged from 3 months to less than 18 years. Talley Adults with COVID-19 who:

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
polatuzumab vedotin 30mg, 140mg powder for concentrate for solution for infusion (Polivy®)	<u>2525</u>	In combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adults with previously untreated diffuse large B-cell lymphoma (DLBCL) who have 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/polatuzu mab-vedotin-polivy-final-may-2023-for-website.pdf	15/08/2023
ropeginterferon alfa-2b 250micrograms/0.5 mL solution for injection in pre-filled pen (Besremi®)	<u>2563</u>	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/ropegint erferon-alfa-2b-besremi-resub-final-june-2023-for-website.pdf	15/08/2023
selumetinib 10mg, 25mg hard capsules (Koselugo®)	<u>2540</u>	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/selumeti nib-koselugo-final-july-2023-for-website.pdf	15/08/2023
Suboxone® 2mg/0.5mg, 8mg/2mg sublingual film (buprenorphine/naloxone)	2316	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction. Restriction: to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.	This medicine is now withdrawn from use/discontinued	15/08/2023
sufentanil citrate 15micrograms sublingual tablets (Zalviso®)	1270/17	Management of acute moderate to severe post- operative pain in adult patients.	This medicine is now withdrawn from use/discontinued	15/08/2023

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Name	Unique identifier	Condition being treated	NHS Grampian decision	Date of decision
sufentanil citrate 30micrograms sublingual tablets (Dzuveo®)		Management of acute moderate to severe post- operative pain in adult patients.	Not routinely available in NHS Grampian	15/08/2023
tezepelumab 210mg solution for injection in pre-filled syringe (Tezspire®)	<u>2541</u>	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.	Not routinely available as the ADTC is waiting for further advice from local clinical experts	15/08/2023
trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®)	<u>2545</u>	As monotherapy for the treatment of adults with unresectable or metastatic HER2-positive breast cancer 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/trastuzu mab-deruxtecan-enhertu-final-march-amended-030423-for- website.pdf	15/08/2023

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