NHS Borders: New Medicines Decisions APRIL 2021 – MARCH 2022

Please note: We are happy to consider requests for other languages or formats. Please contact Pharmacy Admin Office kate.warner@borders.scot.nhs.uk

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

- accepted for use in NHSScotland 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 is responsible for advising the health board on all aspects of the use of medicines.
Medicines routinely available within a health board are usually included in the local formulary. The formulary is a list of medicines for use in the health board that has been agreed by 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.

Why is a particular medicine not routinely available in my health board?

- This is usually because the medicine is not recommended for use in NHSScotland 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 in 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 my health board?

- If a medicine is not routinely available and included on your health board's 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.

NHS Borders board decisions – six options:

- Routinely available in line with national guidance (link to SMC advice)
- Routinely available in line with local guidance for prescribing (link, if desired, to local or regional guidance)
- Routinely available from a specialist centre in another NHS board
- Not routinely available as not recommended for use in NHSScotland (link to relevant SMC advice)
- Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local or regional guidance)
- Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by *(enter date)*

The following table lists NHS Borders decisions on new medicines, ordered by MONTH of decision and then A-Z.
If you need more information on medicines decisions in NHS Borders, please email Formulary Pharmacist liz.leitch@borders.scot.nhs.uk.

APRIL 2021				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
Acalabrutinib Calquence SMC2346	ADVICE: following an abbreviated submission **acalabrutinib (Calquence®)** is accepted for restricted use within NHSScotland. Indication under review: as monotherapy or in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). SMC restriction: as monotherapy for the treatment of adult patients with previously untreated CLL who have a 17p deletion or TP53 mutation and in whom chemo-immunotherapy is unsuitable. Acalabrutinib offers an additional treatment choice in the therapeutic class of Bruton tyrosine kinase inhibitor in this setting. Another medicine within this therapeutic class has been accepted via the end of life and orphan medicine process. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. For SMC advice relating to the use of acalabrutinib in previously untreated adults with CLL outwith the restriction described above, please refer to SMC2347.	12/04/2021	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/acalabrutinib-calquence-abb-smc2346/	28/04/2021
Acalabrutinib Calquence SMC2348	ADVICE: following an abbreviated submission **acalabrutinib (Calquence®)** is accepted for restricted use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. SMC restriction: For adults with relapsed/refractory CLL who have had at least one previous therapy, in whom chemo-immunotherapy is unsuitable. Acalabrutinib offers an additional treatment choice in the therapeutic class of BTK inhibitor in this setting. Another medicine within this therapeutic class has been accepted via the end of life and orphan medicine process. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.	12/04/2021	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/acalabrutinib-calquence-abb-smc2348/	28/04/2021
Ataluren Translarna	Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older. The presence of a nonsense mutation in the dystrophin gene should be determined by	12/04/2021	Full Submission – Ultra-Orphan Medicine with PAS https://www.scottishmedicines.org.uk/medicines-	28/04/2021

SMC2327	genetic testing.		advice/ataluren-translarna-uo-pathway-smc2327/ *Scottish Government will notify Health Boards when this medicine is available for prescribing within the ultra-orphan pathway. Meantime any requests to access treatment should be considered through local non-formulary processes.*	
Dapagliflozin Forxiga SMC2322	ADVICE: following a full submission **dapagliflozin (Forxiga®)** is accepted for use within NHSScotland. Indication under review: in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction. In a randomised, double-blind, phase III study, dapagliflozin demonstrated a significant reduction in the composite outcome of hospitalisation for heart failure, urgent heart failure visit and cardiovascular death compared with placebo in patients with heart failure with reduced ejection fraction receiving current standard of care.	12/04/2021	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-advice/dapagliflozin-forxiga-full-smc2322/	28/04/2021
Dupilumab Dupixent SMC2317	ADVICE: following a full submission **dupilumab (Dupixent®)** is accepted for restricted use within NHSScotland. Indication under review: in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. SMC restriction: for the treatment of patients with blood eosinophils ≥150 cells/microlitre and FeNO ≥25 parts per billion, and ≥4 exacerbations in the preceding year, who have previously received biologic treatment with anti-IgE or anti-IL-5 therapies. In a phase III study dupilumab, compared with placebo, reduced asthma exacerbation rates and was associated with greater improvements in lung function, in patients with asthma uncontrolled with medium to high dose ICS plus one or two controller medicines. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.	12/04/2021	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/dupilumab-dupixent-full-smc2317/	28/04/2021
Galcanezumab Emgality	ADVICE: following a full submission **galcanezumab (Emgality®)** is accepted for restricted use within NHSScotland. Indication under review: prophylaxis of migraine in adults who have at least 4 migraine days per month. SMC restriction: for the treatment of patients with chronic and episodic migraine who	12/04/2021	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/galcanezumab-emgality-full-smc2313/	28/04/2021

SMC2313	have had prior failure on three or more migraine preventive treatments. In studies in patients with episodic and chronic migraine, galcanezumab significantly reduced the number of migraine days per month compared with placebo. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.			
Isatuximab Sarclisa SMC2303	ADVICE: following a full submission under the end of life and orphan equivalent process **isatuximab (Sarclisa®)** is accepted for restricted use within NHSScotland. Indication under review: in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy. SMC restriction: patients receiving fourth-line therapy. Addition of isatuximab to pomalidomide plus dexamethasone significantly increased progression-free survival (PFS) in adults with RRMM who had received at least two prior lines of therapy including lenalidomide and a PI. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	12/04/2021	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/isatuximab-sarclisa-full-smc2303/	28/04/2021

MAY 2021				
Medicine	**Condition being treated**	**Date SMC Advice Published**	**NHS BORDERS decision**	**Date NHSB Decision**
5-aminolevulinic acid Alacare SMC2353	ADVICE: following an abbreviated submission **5-aminolevulinic acid (Alacare®)** is accepted for use within NHSScotland. Indication under review: Single use treatment of mild actinic keratoses lesions with a maximum diameter of 1.8 cm on the face and scalp (hairless areas). Alacare® medicated plaster is another licensed formulation of 5-aminolevulinic acid and may be associated with a small net budget impact.	07/06/2021	Not routinely available https://www.scottishmedicines.org.uk/medicines-advice/5-aminolevulinic-acid-alacare-abb-smc2353/	23/06/2021
Acalabrutinib	ADVICE: following a full submission **acalabrutinib (Calquence®)** is accepted for restricted use within NHSScotland. Indication under review: as monotherapy or in	07/06/2021	Routinely available in line with national guidance https://www.scottishmedicines.org.uk/medicines-	23/06/2021

Calquence SMC2347	combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). SMC restriction: as monotherapy for the treatment of adult patients with previously untreated CLL without a del(17p) or TP53 mutation and who are ineligible for fludarabine, cyclophosphamide and rituximab (FCR) therapy. Acalabrutinib, compared with chlorambucil-obinutuzumab, significantly improved progression-free survival in adults with previously untreated CLL with co-morbidities. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. For SMC advice relating to the use of acalabrutinib as monotherapy for the treatment of adult patients with previously untreated CLL who have a del(17p) or TP53 mutation and in whom chemo-immunotherapy is unsuitable please refer to SMC2346.		advice/acalabrutinib-calquence-full-smc2347/	
Baricitinib Olumiant SMC2337	ADVICE: following a full submission **baricitinib (Olumiant®)** is accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy. SMC restriction: treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy who have failed at least one current systemic immunosuppressant due to intolerance, contraindication or inadequate disease control. Four phase III studies demonstrated superiority of baricitinib in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.	07/06/2021	Not yet decided (July2021) https://www.scottishmedicines.org.uk/medicines-advice/baricitinib-olumiant-full-smc2337/	23/06/2021
Mogamulizumab Poteligeo SMC2336	ADVICE: following a full submission assessed under the orphan medicine process **mogamulizumab (Poteligeo®)** is accepted for restricted use within NHSScotland. Indication under review: treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy. SMC restriction: for the treatment of patients with advanced MF or SS (stage ≥IIB MF and all SS) following at least one prior systemic therapy, who are clinically ineligible for or refractory to treatment with brentuximab vedotin. In an open-label phase III study, mogamulizumab, compared with a histone	07/06/2021	Not yet decided (July2021) https://www.scottishmedicines.org.uk/medicines-advice/mogamulizumab-poteligeo-full-smc2336/	23/06/2021

	deacetylase (HDAC) inhibitor, was associated with a significant improvement in progression-free survival. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			
Nintedanib Ofev SMC2331	ADVICE: following a full submission considered under the orphan equivalent process: **nintedanib (Ofev®)** is accepted for use within NHSScotland. Indication under review: in adults for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype other than idiopathic pulmonary fibrosis (IPF). Nintedanib, compared with placebo, slowed the decline in forced vital capacity (FVC) in adults with non-IPF progressive fibrosing ILD. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	07/06/2021	Not yet decided (July2021) https://www.scottishmedicines.org.uk/medicines-advice/nintedanib-ofev-full-smc2331/	23/06/2021
Ramucirumab Cyramza SMC2291	ADVICE: in the absence of a submission from the holder of the marketing authorisation **ramucirumab (Cyramza®)** is not recommended for use within NHSScotland. Indication under review: in combination with erlotinib for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	07/06/2021	Not routinely available as not recommended for use in NHSScotland https://www.scottishmedicines.org.uk/medicines-advice/ramucirumab-cyramza-nonsub-smc2291/	23/06/2021
Trifluridine/tipiracil Lonsurf SMC2329	ADVICE: following a full submission assessed under the orphan equivalent and end of life process **trifluridine/tipiracil (Lonsurf®)** is accepted for restricted use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease. SMC restriction: for use as third line treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction. In a phase III, randomised, double-	07/06/2021	Not yet decided (July 2021) https://www.scottishmedicines.org.uk/medicines-advice/trifluridinetipiracil-lonsurf-full-smc2329/	23/06/2021

	blind study, trifluridine/tipiracil was associated with an improvement in overall survival compared with placebo. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.			
Vigabatrin Kigabeq SMC2352	ADVICE: following an abbreviated submission **vigabatrin (Kigabeq®)** is accepted for restricted use within NHSScotland. Indication under review: In infants and children from 1 month to less than 7 years of age for: - Treatment in monotherapy of infantile spasms (West's syndrome). - Treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated. SMC restriction: patients in whom other formulations of vigabatrin are not suitable. Vigabatrin 500mg soluble tablets are considered bioequivalent to vigabatrin 500mg granules for oral solution. Vigabatrin soluble tablets are more expensive than vigabatrin granules for oral solution. Overall net budget impact is likely to be small.	07/06/2021	Not yet decided (July 2021) https://www.scottishmedicines.org.uk/medicines-advice/vigabatrin-kigabeq-abb-smc2352/	23/06/2021
Paediatric Licence Extensions		07/06/2021	PASAG (Paediatric Licence Extensions) 2	

Product	Company	Paediatric indication	CHMP positive opinion[1]	Adults/older age group		NHS Boards Informed
				SMC advice	PAS	
glecaprevir / pibrentasvir (Maviret)	AbbVie	Treatment of chronic hepatitis C virus (HCV) infection in children aged 3 years and older	212239/2021 (22 Apr-21)	Accepted 1278/17	Yes	May-21
teriflunomide (Aubagio	Sanofi	Treatment of paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis. SMC accepted restricted advice in adult population	213201/2021 (22 Apr-21)	Accepted restricted 940/14	Yes	May-21

Amended advice - niraparib 100mg hard capsules (Zejula®) GlaxoSmithKline UK SMC2338 - Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for niraparib (Zejula®), as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III or IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. The DAD will be published on Monday 10 May 2021.