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ADTC Newsletter

New Drugs and Therapeutic Advances

Outlined in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix 1).
Please remember that the ADTC advises prescribers **not** to prescribe any drug that has not been recommended by Scottish Medicines Consortium (SMC) or has not yet been considered by SMC.

Where a medicine is not recommended for use by the Scottish Medicines Consortium (SMC) for use in NHS Scotland, including those medicines not recommended due to non-submission, this will be noted by the Area Drug and Therapeutics Committee New Drugs & Formulary Subgroup and the medicine will not be added to the NHS Forth Valley Formulary.

Where a medicine that has not been accepted by the SMC or NHS Health Improvement Scotland (HIS) following their appraisal on clinical and cost-effectiveness, there are Individual Patient Treatment Request (IPTR) and Peer Approved Clinical System (PACS) processes which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to pursue approval for prescribing, on a “case by case” basis for individual patients

A copy of these policies can be found at the Pharmacy page on the Quality Improvement Website on the following link: https://staffnet.fv.scot.nhs.uk/guidelines/pharmacy-and-precribing/

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the Quality Improvement Website on the link below.

https://staffnet.fv.scot.nhs.uk/guidelines/

Drugs Not Approved By the Scottish Medicines Consortium

Prescribing of SMC non-recommended drugs is monitored nationally by the Information Services Directorate (ISD) of the NHS National Services Scotland and reported to the Forth Valley Primary Care Pharmacy Services. As part of our locally agreed process, practices will be routinely notified on a quarterly basis of any items which are not recommended for use, and advised to review therapy.

The Acute Services will similarly be monitoring the use of SMC non-recommended drugs and will feedback usage to their Executives via the Finance Report.

All information provided by this newsletter constitutes the most current advice of the Forth Valley Area Drug and Therapeutic Committee. All SMC information and decisions are correct at time of issue but may be liable to change in the future.
For full **SMC advice** on specific drugs please refer to the SMC website www.scottishmedicines.org

Category Classification

Drugs Approved / Not Recommended By SMC

Category 1	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
Category 2	Available in line with local guidance for prescribing
Category 3	Available from a specialist centre in another NHS Board
Category 4	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Category 5	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 guidance if appropriate)
Category 6	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Avalglucosidase alfa 100mg powder for concentrate for solution for infusion (Nexviadyme®) SMC Number 2546 https://www.scottishmedicines.org.uk/media/7700/avalglucosidase-alfa-nexviadyme-abb-final-june-2023-for-website.pdf	**Accepted for use** within NHSScotland. **Indication under review:** long-term enzyme replacement therapy for the treatment of patients with Pompe disease (acid α-glucosidase deficiency)	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Bempedoic acid 180mg film-coated tablets (Nilemdo®) SMC Number 2363 https://www.scottishmedicines.org.uk/media/6104/bempedoic-acid-nilemdo-resubmission-final-june-2021-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or • Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contra-indicated. **SMC restriction:** for use in combination with ezetimibe in patients who are: • statin intolerant or for whom a statin is contra-indicated and • where ezetimibe alone does not appropriately control LDL-C and • where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 1 –** available in line with national guidance	Specialist initiation and recommendation by the lipid clinic and continuation in Primary Care.
Bempedoic acid / ezetimibe 180mg / 10mg film-coated tablets (Nustendi®) SMC Number 2406 https://www.scottishmedicines.org.uk/media/6330/bempedoic-acid-ezetimibe-nustendi-abbreviated-final-sept-2021-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe, • alone in patients who are either statin-intolerant or for whom a	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 1 –** available in line with national guidance	Specialist initiation and recommendation by the lipid clinic and continuation in Primary Care.

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
	statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone • in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin. **SMC restriction**: for use in patients who are: • statin intolerant or for whom a statin is contra-indicated and • where ezetimibe alone does not appropriately control LDL-C and • where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate			
Bulevirtide 2mg powder for solution for injection (Hepcludex®) SMC Number 2520 https://www.scottishmedicines.org.uk/media/7451/bulevirtide-hepcludex-final-feb-2023-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication Under Review:** for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease. **SMC restriction:** to use in patients with evidence of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Estradiol 1mg / micronised progesterone 100mg capsules (Bijuve®) SMC Number 2502 https://www.scottishmedicines.org.uk/media/7098/estradiol-micronised-progesterone-bijuve-abb-final-aug-2022-for-website.pdf	**Accepted for use** within NHSScotland. **Indication under review:** 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	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Faricimab 120mg/mL solution for injection (Vabysmo®) SMC Number 2499 https://www.scottishmedicines.org.uk/media/7205/faricimab-vabysmo-final-oct-2022docxfor-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO) **SMC restriction**: 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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Metreleptin powder for solution for injection (Myalepta®) SMC Number 2559 https://www.scottishmedicines.org.uk/media/7610/umar-metreleptin-myalepta-final-may-2023-for-website.pdf	**Indication under review:** as an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients with: • confirmed congenital generalised LD (Berardinelli-Seip syndrome) or acquired generalised LD (Lawrence syndrome) in adults and children 2 years of age and above. • confirmed familial partial LD or acquired partial LD (Barraquer-Simons syndrome), in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control. *The Scottish Medicines Consortium (SMC) has completed its initial assessment of the evidence for the above product using the ultra-orphan framework:*	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 3 –** available from a specialist centre in another Health Board	N/A
Nintedanib soft capsules (Ofev®) SMC Number 2513 https://www.scottishmedicines.org.uk/media/7449/nintedanib-ofev-resub-final-feb-2023-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication Under Review:** in adults for the treatment of idiopathic pulmonary fibrosis (IPF). **SMC Restriction:** For use in patients with a predicted forced vital capacity (FVC) >80%	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia®) SMC Number 2478 ozanimod-zeposia-final-sept-2022-for-website.pdf (scottishmedicines.org.uk)	**Accepted for use** within NHSScotland. **Indication under review**: 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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 5** – 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	N/A
Patiromer sorbitex calcium 8.4g and 16.8g powder for oral suspension (Veltassa®) SMC Number 2568 https://www.scottishmedicines.org.uk/media/7508/patiromer-veltassa-abbreviated-final-march-2023-amended-040423-for-website.pdf	**Accepted for restricted** use within NHSScotland. **Indication under review:** treatment of hyperkalaemia in adults. **SMC** restriction: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Rimegepant oral lyophilisate (Vydura®) **SMC Number 2521** https://www.scottishmedicines.org.uk/media/7565/rimegepant-vydura-acute-final-april-2023docxfor-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication Under Review:** for the acute treatment of migraine with or without aura in adults. **SMC restriction:** for patients who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 5** – 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	N/A
Roxadustat 20mg, 50mg, 70mg, 100mg and 150mg film-coated tablets (Evrenzo®) **SMC Number 2461** https://www.scottishmedicines.org.uk/media/7041/roxadustat-evrenzo-final-july-2022-for-website.pdf	**Accepted for restricted** use within NHSScotland. **Indication under review:** treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD). **SMC restriction:** for use in patients who are non-dialysis dependent (NDD) at the time of treatment initiation.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 2 –** available in line with local guidance for prescribing	Would be initiated and prescribed by the renal unit until the patient has been stabilised on a dose. Ongoing prescribing would be continued in primary care with ongoing monitoring and review to be carried out by the renal specialists.
Sodium zirconium cyclosilicate 10g powder for oral suspension (Lokelma®) **SMC Number 2515** https://www.scottishmedicines.org.uk/media/7208/sodium-zirconium-lokelma-abb-final-oct-2022docxfor-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** for the treatment of hyperkalaemia in adult patients **SMC restriction:** in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Upadacitinib 15mg, 30mg, and 45mg prolonged-release tablets (Rinvoq®) **SMC Number 2510** upadacitinib-rinvoq-uc-abb-final-sept-2022-for-website.pdf (scottishmedicines.org.uk)	**Accepted for use** within NHSScotland. **Indication under review:** 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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 5** – 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	N/A

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Upadacitinib 15mg prolonged-release tablets (Rinvoq®) SMC Number 2495 https://www.scottishmedicines.org.uk/media/7295/upadacitinib-rinvoq-resub-final-nov-2022-amended-081222-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** 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. **SMC restriction:** 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 a phase III randomised, placebo-controlled and active comparator study in patients who had an inadequate response to methotrexate, upadacitinib significantly improved the signs and symptoms of RA compared with placebo.	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Upadacitinib 15mg prolonged-release tablets (Rinvoq®) SMC Number 2532 https://www.scottishmedicines.org.uk/media/7407/upadacinib-rinvoq-nr-axspa-abb-final-jan-2023-for-website.pdf	**Accepted for use** within NHSScotland. **Indication under review:** 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).	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	
Upadacitinib 15mg, 30mg and 45mg prolonged-release tablets (Rinvoq®) SMC Number 2575 https://www.scottishmedicines.org.uk/media/7611/upadacitinib-rinvoq-abbreviated-final-may-2023-for-website.pdf	**Accepted for use** within NHSScotland. **Indication under review:** for the treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent, or for whom such therapies are not advisable.	**Category 6** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Decision Pending**	

SMC NOT RECOMMENDED – The following drugs for the indication stated are all classified as **Category 4** i.e. Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)	
Icosapent ethyl soft capsules (Vazkepa®) **SMC Number 2531**	**Indication under review:** 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.
Rimegepant oral lyophilisate (Vydura®) **SMC Number 2567**	**Indication under review:** for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month**.**
Tafasitamab powder for concentrate for solution for infusion (Minjuvi®) **SMC Number 2522**	**Indication Under Review:** in combination with lenalidomide followed by tafasitamab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Formulary Changes/Additions/Amendments

The following key changes to the Forth Valley Formulary have been agreed by the New Drugs & Formulary Group following recent formulary section reviews. Relevant *ScriptSwitch*® messages to support prescribers in primary care have been added to the clinical system and relevant changes will be reflected in the EMIS FV e-Formulary when it is next updated.

The Forth Valley Formulary can be accessed from the staff net homepage under quick links - click on clinical resources then FV formulary or access via the intranet link Forth Valley Formulary or via the Forth Valley Formulary internet site https://pharmacies.nhsforthvalley.com/local-guidance/forth-valley-formulary/

Formulary Changes

- ***Emerade®***
  This product has been discontinued by the manufacturer, therefore this has been removed from the Forth Valley Formulary. The formulary choices now are Jext® and Epipen® with Jext® being the most cost effective option.

- ***Sandocal®***
  Sandocal's® name was changed a few years ago to Calvive® , the formulary will be changed to reflect this. The cost remains the same.

- ***Anthelios SPF 50+® sun protection lotion***
  This is an ACBS product which can be prescribed for certain medical conditions. This was discontinued by the mafufacturer a few years ago and was removed from the formulary, but has now been relaunched. Due to the supply problems with similar products this has been added back into the formulary.

Process Flowchart (Appendix 1)

NHS FORTH VALLEY PRESCRIBING OF NEW MEDICINES FLOWCHART

This flowchart outlines the NHS Forth Valley process for the prescribing of new medicines. This follows guidance from the Scottish Government for the managed introduction and availability of newly licensed medicines in NHS Scotland