Edition: July 2025
Volume: 22 No:2

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 on the FV Clinical Guidelines page:
FV Clinical Guidelines - Guidelines - Pharmacy & Prescribing Guidelines

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the FV Clinical Guidelines page:
FV Clinical Guidelines - Guidelines - Pharmacy & Prescribing 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**
Tirzepatide (Mounjaro®) SMC number 2653	**Indication under review:** For weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial Body Mass Index (BMI) of ≥30 kg/m^2 (obesity) or ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus). **SMC restriction:** for use in adults with BMI ≥30 kg/m^2* and at least one weight-related comorbidity. **a lower BMI cut-off may be more appropriate for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population.*	**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	Currently N/A until decision has been made
Lebrikizumab (Ebglyss®) SMC number 2707	**Indication under review:** for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy. SMC restriction: patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable and where a biologic would otherwise be offered. Four phase III studies demonstrated superiority of lebrikizumab 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.	**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	Secondary Care only

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Bismuth subcitrate potassium/ Metronidazole/ Tetracycline hydrochloride hard capsules (Pylera®) SMC number 2701	**Indication under review:** In combination with omeprazole, for the eradication of Helicobacter pylori and prevention of relapse of peptic ulcers in patients with active or a history of H. pylori associated ulcers SMC restriction: restricted to use in accordance with clinical guidelines for the eradication of H. pylori Pylera® is a new combination medicine of existing medicines, with limited net budget impact.	**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	Primary Care and Secondary Care
Vibegron (Obgemsa®) SMC number 2696	**Indication under review:** symptomatic treatment of adult patients with overactive bladder (OAB) syndrome. Vibegron offers an additional treatment choice in the therapeutic class of beta-3 adrenergic receptor agonists in this setting.	**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	Secondary Care initiated ongoing prescribing in Primary Care
Vamorolone (Agamree®) SMC number 2721	**Indication under review:** treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older. In a randomised, double-blind, phase IIb study, treatment with vamorolone resulted in a significant improvement in the change in time to stand from supine (TTSTAND) velocity and change in 6-minute walk test (6MWT) distance between baseline and week 24, 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	**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
Danicopan (Voydeya®) SMC number 2675	**Indication under review:** as an add-on to ravulizumab or eculizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have residual haemolytic anaemia. SMC restriction: under the advice of the national PNH service. In a randomised phase III study, danicopan, as an add-on treatment to C5 inhibitor, was associated with a statistically significant improvement in haemoglobin concentrations at week 12 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	**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**
Iptacopan (Fabhalta®) SMC number 2676	**Indication under review:** As monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia. SMC restriction: under the advice of the national PNH service. In an open-label phase III study in patients with PNH who had persistent anaemia despite treatment with anti-C5 treatment iptacopan significantly increased the proportion of patients whose haemoglobin levels improved by at least 2 g/dL and the proportion of patients with haemoglobin levels greater than or equal to 12 g/dL, compared with anti-C5 treatment. In a single-arm phase III study in patients who had not received anti-C5 treatment, 92% of patients had an increase in haemoglobin of at least 2 g/dL after 24 weeks.	**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
Ciclosporin (Cequa®) SMC number 2739	**Indication under review:** treatment of moderate-to-severe Dry Eye Disease (keratoconjunctivitis sicca) in adult patients who have not responded adequately to artificial tears. **SMC restriction:** severe keratitis in adult patients with Dry Eye Disease.	**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
Risankizumab (Skyrizi®) SMC number 2686	**Indication under review:** for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy. Risankizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors.	**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**
Ublituximab (Briumvi®) SMC number 2731	**Indication under review:** treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features**. SMC restriction:** treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features. Ublituximab offers an additional treatment choice in the therapeutic class of anti-CD20 monoclonal antibodies.	**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	Secondary Care only
Crovalimab (PiaSky®) SMC number 2728	**Indication under review:** as monotherapy for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity. • In patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months. **SMC restriction:** under the advice of the national PNH service Crovalimab offers an additional treatment choice in the therapeutic class of complement C5 inhibitors. Another complement C5 inhibitor was accepted for restricted use under the orphan equivalent process.	**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
Cabotegravir (Apretude®) SMC number 2718	**Indication under review:** in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg. Cabotegravir tablets: in combination with safer sex practices for short term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg. Cabotegravir tablets may be used as:	**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	Secondary Care only

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
	· oral lead-in to assess tolerability of cabotegravir prior to administration of long acting cabotegravir injection. · oral PrEP for individuals who will miss planned dosing with cabotegravir injection. **SMC restriction:** Adults and adolescents (weighing at least 35kg) at high risk of sexually acquired HIV who are eligible for PrEP, including oral PrEP, but for whom oral PrEP is not appropriate to meet their HIV prevention needs. Cabotegravir was superior to daily oral tenofovir disoproxil fumarate/emtricitabine in the reduction of incident HIV acquisitions in a phase IIb/III study in men who have **sex** with men and transgender women (HPTN 083) and in a phase III study in cisgender women (HPTN 084) at high risk of acquiring human immunodeficiency virus (HIV).			
Netarsudil plus latanoprost (Roclanda®) SMC number 2720	**Indication under review:** for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction. **SMC restriction:** for use in patients for whom treatment with a prostaglandin analogue alone provides insufficient IOP reduction, only if: · the patient has then tried a fixed-dose combination treatment and it has not sufficiently reduced IOP, or · a fixed-dose combination treatment containing beta-blockers is unsuitable.	**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**	Currently N/A until decision has been made

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Fenfluramine (Fintepla®) SMC 2723	**Indication under review**: treatment of seizures associated with Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. **SMC restriction:** patients whose seizures have not been controlled after trying two or more anti-epileptic medicines.	**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
Bimekizumab (Bimzelx®) SMC number 2698	**Indication under review:** for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy**. SMC restriction:** for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.	**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	Secondary Care only
Elafibranor (Iqirvo®) SMC number 2714	**Indication under review:** for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.	**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	Secondary Care only
Eplontersen (Wainzua®) SMC number 2755	**Indication under review:** for the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv amyloidosis) in adult patients with Stage 1 and 2 polyneuropathy. Eplontersen offers an additional treatment choice of transthyretin (TTR) gene silencer for this indication.	**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**
Bevacizumab gamma (Lytenava®) SMC 2744	**Indication under review:** in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD).	**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
Ruxolitinib (Jakavi®) SMC 2750	**Indication under review:** for the treatment of patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids.	**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
Mepolizumab (Nucala®) SMC 2765 ***Updated advice***	**Indication under review:** as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older. **SMC restriction:** patients who have eosinophils of at least 150 cells per microlitre (0.15 x 10^9/L) at initiation of treatment and have had at least three asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids.	**Category 1 -** Available in line with national guidance	**Category 1 -** Available in line with national guidance	Secondary Care only

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Cladribine (Mavenclad®) SMC 2751 ***Updated advice***		**Category 2 -** Available in line with local guidance	**Category 2 -** Available in line with local guidance	Secondary Care only
Nirmatrelvir and ritonavir (Paxlovid) SMC 2557 ***Updated advice***		**Category 1 -** Available in line with national guidance	**Category 1 -** Available in line with national guidance	Secondary Care only
Dapagliflozin (Forxiga®) SMC number 2763 ***Updated advice***	**Indication under review:** in adults for the treatment of chronic kidney disease (CKD) **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 20 mL/min/1.73m2 up to 45 mL/min/1.73m2, or · an eGFR of 45 mL/min/1.73m2 up to 90 mL/min/1.73m2 and either: o A urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or o Type 2 Diabetes Mellitus (T2DM). Dapagliflozin offers an additional treatment choice in the therapeutic class of sodium-glucose co-transporter 2 (SGLT2) inhibitor.	**Category 2 -** Available in line with local guidance	**Category 2 -** Available in line with local guidance	Primary and Secondary Care
Rimegepant (Vydura) SMC 2603	**Indication under review:** for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month. **SMC restriction:** for patients with episodic migraine who have at least 4 migraine attacks per month, but fewer than 15 headache days per month and who have had prior failure on three or more migraine preventive treatments	**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	Secondary Care initiated ongoing prescribing in Primary Care

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)	
Spesolimab (Spevigo®) SMC number 2729	**Indication under review**: for the treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy.
Donanemab (Kisunla®) SMC number 2687	**Indication under review:** for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease (AD) in adult patients that are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers.
Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide (Genvoya) SMC number 2809	**Indication under review:** treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in paediatric patients aged from 2 years and with body weight at least 14 kg to less than 25 kg.
Sarilumab (Kevzara®) SMC number 2810	**Indication under review:** treatment of polymyalgia rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper.

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.

Formulary Changes

Formulary Additions

- Sodium Hyaluronate preferred brand changed to (Xailin Tears 0.1% HA, Xailin 0.2% Plus, Ocufresh Intense Relief 0.4%)
- Liraglutide preferred brand changed to Diavic and Zegluxen

Formulary Deletions

- Phosex (calcium acetate) 1000mg tablets – Brand discontinued
- Victoza brand removed as discontinued
- Alogliptin

Lidocaine medicated plasters

Lidocaine plasters should only be prescribed in NHS Forth Valley under the following circumstances:

- To individuals who have been treated in line with SMC guidance and are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN).
- Where the decision to prescribe is in line with the Scottish Palliative Care guideline.

Use of lidocaine medicated plasters for any indication, other than those listed above, would be considered non-formulary. The prescribing of lidocaine plasters for any indication other than the symptomatic relief of neuropathic pain associated with previous herpes zoster infection in adults would be considered off-label.

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