Edition: March 2025
Volume: 22 No:1

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
Faricimab (Vabysmo®) SMC number 2685	**Indication under review:** treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO). Faricimab offers an additional treatment choice in the therapeutic class of antineovascularisation agents.	**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	Secondary Care only
Rezafungin acetate (Rezzayo®) SMC number 2659	**Indication under review:** for the treatment of invasive candidiasis in adults. **SMC restriction**: use should be on the advice of local microbiologists or specialists in infectious 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 2-** Available in line with local guidance for prescribing	Secondary Care only – **Prescribing restricted to Microbiology and Infectious Diseases only**.
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	**Category 6 –** Not routinely available as local implementation plans are being	**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**
	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.	developed or the ADTC is waiting for further advice from local clinical experts		
Somapacitan (Sogroya) SMC number 2629	**Indication under review:** for the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD). SMC restriction: for children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (paediatric GHD). Somapacitan offers an additional treatment choice in the therapeutic class of recombinant human growth hormones 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 2-** Available in line with local guidance for prescribing	Secondary Care only until a shared care agreement is in place for prescribing in Primary Care. **(Please note this submission is for paediatric prescribing only)**
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	**Decision pending**	Currently N/A until decision has been made
Linzagolix (Yselty®) SMC number 2631	**Indication under review:** the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	**Category 6 –** Not routinely available as local implementation	**Category 1-** Available in line with national guidance	Secondary Care initiated and ongoing

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
	SMC restriction: for use in patients when conventional first-line treatments (such as tranexamic acid, hormonal contraceptives and intrauterine devices) have failed or are considered unsuitable. Treatment with linzagolix, with and without hormonal add-back therapy (ABT), resulted in statistically significant and clinically meaningful reductions in menstrual blood loss, compared with placebo.	plans are being developed or the ADTC is waiting for further advice from local clinical experts		prescribing in Primary 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	**Decision pending**	Currently N/A until decision has been made
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	**Decision pending**	Currently N/A until decision has been made
Sirolimus (Hyftor®) SMC number 2710	**Indication under review:** for the treatment of facial angiofibroma associated with tuberous sclerosis complex in adults and paediatric patients aged 6 years and older. In a randomised phase III study, sirolimus gel demonstrated a statistically significant improvement in facial angiofibromas 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 (link	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**
			to local guidance)	
Relugolix, estradiol, norethisterone acetate film-coated tablets (Ryeqo®) SMC number 2666	**Indication under review:** in adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis. Relugolix, estradiol, norethisterone acetate film-coated tablets (Ryeqo®), compared with placebo, resulted in statistically and clinically significant improvements in treatment response (menstrual and non-menstrual pelvic pain) after 24 weeks in women with moderate-to-severe pain associated with endometriosis	**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 initiated and ongoing prescribing in Primary Care
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	**Decision pending**	Currently N/A until decision has been made
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	**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**
	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.			
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	**Decision pending**	Currently N/A until decision has been made
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	**Decision pending**	Currently N/A until decision has been made
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	**Decision pending**	Currently N/A until decision has been made
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	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice	**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**
	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.	from local clinical experts		

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)	
Bictegravir / emtricitabine / tenofovir alafenamide (Biktarvy®) SMC number 2760	**Indication under review:** treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients at least 2 years of age and weighing at least 14 kg to less than 25 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.
Rozanolixizumab (Rystiggo®) SMC number 2761	**Indication under review:** as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
Lecanemab (Leqembi®) SMC number 2700	**Indication under review:** for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E ε 4 (ApoEε4) heterozygotes or non-carriers.

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 Deletions

- Neutrogena® T/Gel® Therapeutic 2% shampoo (Discontinued Feb 2025)

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