Edition: December 2024
Volume: 21 No:4

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**
Dupilumab (Dupixent®) SMC number 2317	**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.	**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
Tezepelumab (Tezspire®) SMC number 2541	**Indication under review:** 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. Compared with placebo, the addition of tezepelumab to inhaled corticosteroids and at least one additional controller medicine, significantly reduced the annual asthma exacerbation rate in patients with inadequately controlled	**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

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Foslevodopa-foscarbidopa 240mg/mL + 12mg/mL solution for infusion (Produodopa®) SMC number 2574	**Indication under review:** treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. **SMC restriction:** for use in patients not eligible for deep brain stimulation (DBS).	**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
Ozanimod (Zeposia®) SMC number 2478	**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	**Decision pending**	Currently N/A until decision has been made
Etrasimod (Velsipity®) SMC number 2655	**Indication under review:** for the treatment of patients 16 years of age and older 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 biological agent. Etrasimod offers an additional treatment choice in the therapeutic class of sphingosine 1-phosphate (S1P) receptor modulators.	**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
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,	**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**
	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.*			
Empagliflozin (Jardiance) SMC number 2642	**Indication under review:** in adults for the treatment of chronic kidney disease. **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/1.73m^2 up to 45 mL/min/1.73m^2, or an eGFR of 45 mL/min/1.73m^2 up to 90 mL/min/1.73m^2 and either: A urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or Type 2 Diabetes Mellitus (T2DM).	**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 and Primary Care
Tezacaftor-ivacaftor (Symkevi®) SMC number 2711	**Indication under review:** in a combination regimen with ivacaftor tablets for the treatment of patients with cystic fibrosis (CF) aged 6 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.	**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 NHS Board	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**
Lumacaftor-ivacaftor (Orkambi®) SMC number 2712	**Indication under review:** treatment of cystic fibrosis (CF) in patients aged 1 year and older (granules in sachet) or 6 years and older (film-coated tablets) who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	**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 NHS Board	N/A
Ivacaftor-tezacaftor-elexacaftor (Kaftrio®) SMC number 2713	**Indication under review:** in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 2 years to less than 6 years (granules in sachet) and 6 years and older (film-coated tablets) who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	**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 NHS Board	N/A
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	**Decision pending**	Currently N/A until decision has been made
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	**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	**Category 6 –** Not routinely available as local implementation	**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**
	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.	plans are being 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	**Decision pending**	Currently N/A until decision has been made
Tenecteplase (Metalyse®) SMC number 2697	**Indication under review:** in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from the last known well and after exclusion of intracranial haemorrhage. Tenecteplase offers an additional treatment choice in the therapeutic class of antithrombotic 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 1 -** Available in line with national guidance	Secondary Care only
Bismuth subcitrate potassium/ Metronidazole/ Tetracycline	**Indication under review:** In combination with omeprazole, for the eradication of Helicobacter pylori and prevention of relapse of peptic ulcers in patients with active	**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**
hydrochloride hard capsules (Pylera®) SMC number 2701	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.	developed or the ADTC is waiting for further advice from local clinical experts		
Linzagolix (Yselty®) SMC number 2631	**Indication under review:** the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. **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.	**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
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

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)	
Drospirenone film coated tablets (Slynd®) SMC number 2725	**Indication under review**: contraception.
Levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon®) SMC number 2507	**Indication under review:** treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results. In a phase I pharmacokinetic study, in patients with advanced levodopa-responsive Parkinson's disease, dose-adjusted levodopa exposure was significantly higher with Lecigon®

	treatment, when compared with levodopa / carbidopa monohydrate intestinal gel.

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 Additions

Formulary Deletions

- **Edoxoban**

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