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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**
Avacopan capsules (Tavneos®) SMC Number 2578 https://www.scottishmedicines.org.uk/media/7938/avacopan-tavneos-final-oct-2023-for-website.pdf	**Indication under review**: In combination with a rituximab or cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).	**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
Foslevodopa-foscarbidopa 240mg/mL + 12mg/mL solution for infusion (Produodopa®) SMC Number 2574 https://www.scottishmedicines.org.uk/media/8162/foslevodopa-foscarbidopa-produodopa-abb-final-feb-2024-for-website.pdf	**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
Sotrovimab (Xevudy®) SMC Number 2557 https://www.scottishmedicines.org.uk/media/7674/20230622-collaborative-advice-document-for-nice-mta878-v30.pdf	**Indication under review:** Treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection	**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
Tocilizumab (RoActemra®) 20mg/ml concentrate for solution for infusion SMC Number 2552 https://www.scottishmedicines.org.uk/media/7674/20230622-collaborative-advice-document-for-nice-mta878-v30.pdf	**Indication under review**: Treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation	**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**
Dupilumab 300mg solution for injection in pre-filled syringe or pre-filled pen (Dupixent®) SMC Number 2598 dupilumab-dupixent-final-jan-2024-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.	**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
Ozanimod (Zeposia®) SMC Number 2478 ozanimod-zeposia-final-sept-2022-for-website.pdf (scottishmedicines.org.uk)	**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
ritlecitinib (Litfulo®) SMC Number 2610 ritlecitinib-litfulo-final-march-2024-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** For the treatment of severe alopecia areata in adults and adolescents 12 years of age and older. In a randomised, double-blind, phase IIb/III study in patients with severe alopecia areata, ritlecitinib was associated with statistically significant improvements in scalp hair regrowth versus placebo at week 24.	**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
tirzepatide (Mounjaro®) SMC Number 2633 tirzepatide-mounjaro-final-march-2024-amended-020424-for-website.pdf	**Indication under review:** for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: •as monotherapy when metformin is considered inappropriate due to intolerance or contraindications •in addition to other medicinal products for the	**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 initiation, can be continued 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**
(scottishmedicines.org.uk)	treatment of diabetes. **SMC restriction**: in addition to other oral anti-diabetic medicines as an option when glucagon-like peptide-1 (GLP-1) receptor agonists would be considered. In three phase III studies, tirzepatide demonstrated statistically significant reductions from baseline in HbA1c compared with a GLP-1 receptor agonist and two basal insulins. SMC cannot recommend the use of tirzepatide as monotherapy when metformin is considered inappropriate due to intolerance or contraindications as the company's submission related only to its use in addition to other medicinal products for the treatment of diabetes.			
difelikefalin (Kapruvia®) **SMC number 2623** difelikefalin (Kapruvia) (scottishmedicines.org.uk)	**Indication under review:** treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis. **SMC restriction:** for use in patients with an inadequate response to best supportive care for reducing itch.	**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
etrasimod (Velsipity®) **SMC number 2655** etrasimod-film-coated-tablets-velsipity-abb-final-may-2024-for-website.pdf (scottishmedicines.org.uk)	**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

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
budesonide/formoterol (Symbicort® Turbohaler®) 200 micrograms/6 micrograms/inhalation, inhalation powder **SMC number 2622** budesonide-formoterol-symbicort-final-april-2024-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** As reliever therapy for adults and adolescents (12 years and older) with mild asthma. SMC restriction: for use in patients who would otherwise receive low dose inhaled corticosteroid (ICS) maintenance therapy plus short-acting beta-2 adrenoceptor agonist (SABA) as needed	**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 and Primary Care
tirzepatide (Mounjaro®) **SMC Number 2653** tirzepatide-mounjaro-final-may-2024-amended-050624-for-website.pdf (scottishmedicines.org.uk)	**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
Empagliflozin (Jardiance) **SMC number 2642** empagliflozin-jardiance-final-june-2024-amended-240624-for-website.pdf	**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:	**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**
(scottishmedicines.org.uk)	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).			
Follitropin delta (Rekovelle®) SMC number 2670 follitropin delta (Rekovelle) (scottishmedicines.org.uk)	**Indication under review:** controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an *in vitro* fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle. **SMC restriction:** for use in normal responders (patients with an anti-Müllerian hormone level of >5.4 pmol/L) or high responders (patients with an anti-Müllerian hormone level of ≥25 pmol/L). Follitropin delta offers an additional treatment choice in the therapeutic class of gonadotropins.	**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 currently or there is a local preference for alternative medicines (link to local guidance)	N/A
Pegunigalsidase alfa (Elfabrio®) SMC number 2665 pegunigalsidase-alfa-elfabrio-final-june-2024-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase). **SMC restriction**: for use in adults with symptomatic Fabry disease who would usually be offered an enzyme replacement therapy. In a two-year, double-blind, randomised, phase III study, pegunigalsidase alfa appeared to have a similar annualised change in estimated glomerular filtration rate (eGFR) compared with an alternative enzyme replacement therapy.	**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 currently or there is a local preference for alternative medicines (link to local guidance)	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**
Remdesivir (Veklury®) **SMC number 2550** 20240510-collaborative-advice-document-remdesivir-v11.pdf (scottishmedicines.org.uk)	**Indication under review: treatment of COVID-19 in:** • adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment). • adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. **SMC restriction:** • adults, only if they have a high risk of serious illness (risk factors as defined in section 5 of NICE's technology appraisal of nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19). • babies, children and young people, only if they: are aged 4 weeks to 17 years and weigh at least 3 kg, and have pneumonia and need supplemental oxygen, or weigh at least 40 kg and have a high risk of serious illness (risk factors as defined in section 5 of NICE's technology appraisal guidance on nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19).	**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 currently or there is a local preference for alternative medicines (link to local guidance)	N/A
etranacogene dezaparvovec (Hemgenix®) **SMC number 2649** etranacogene-dezaparvovec-hemgenix-final-july-2024-amended-070824-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** for the treatment of severe and moderately severe haemophilia B (congenital factor IX deficiency) in adult patients without a history of factor IX inhibitors. In an open-label, non-randomised, single-arm, phase III study, the annualised bleeding rate was reduced following treatment with etranacogene dezaparvovec compared with a lead-in period of regular factor IX prophylaxis.	**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 currently or there is a local preference for alternative medicines (link to local guidance)	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**
Tezacaftor-ivacaftor (Symkevi®) SMC number 2711 20240724-cad-symkevi-smc2711-v10.pdf (scottishmedicines.org.uk)	**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	**Decision pending**	Currently N/A until decision has been made
lumacaftor-ivacaftor (Orkambi®) SMC number 2712 20240724-cad-orkambi-smc2712-v10.pdf (scottishmedicines.org.uk)	**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	**Decision pending**	Currently N/A until decision has been made
Ivacaftor-tezacaftor-elexacaftor (Kaftrio®) SMC number 2713 20240724-cad-kaftrio-smc2713-v10.pdf (scottishmedicines.org.uk)	**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	**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)	
Ruxolitinib (Opzelura®) SMC Number 2634 ruxolitinib-topical-opzelura-final-april-2024-amended-080524-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** for the treatment of non-segmental vitiligo (NSV) with facial involvement in adults and adolescents from 12 years of age.
Tixagevimab and cilgavimab (Evusheld®) SMC Number 2558 20240508-collaborative-advice-document-tixagevimab-and-cilgavimab-v10.pdf (scottishmedicines.org.uk)	**Indication under review:** treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.
Clostridium botulinum neurotoxin type A (Xeomin®) SMC number 2680 https://scottishmedicines.org.uk/media/8380/clostridium-botulinum-neurotoxin-type-a-xeomin-non-sub-final-may-2024-for-website.pdf	**Indication under review:** focal spasticity of the lower limb affecting the ankle joint.
Dupilumab (Dupixent®) SMC number 2682 https://scottishmedicines.org.uk/media/8382/dupilumab-dupixent-non-sub-final-may-2024-for-website.pdf	**Indication under review:** treatment of eosinophilic esophagitis in adults and adolescents 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy.
Lanacapavir (Sunlenca®) SMC number 2691 https://scottishmedicines.org.uk/media/8457/lenacapavir-sunlenca-non-sub-final-june-2024-for-website.pdf	**Indications under review:** Film-coated tablets: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection. Solution for injection: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.
Remimazolam (Byfavo®) SMC number 2692 https://scottishmedicines.org.uk/media/8462/remimazolam-byfavo-non-sub-final-june-2024-for-website.pdf	**Indication under review**: in adults for intravenous induction and maintenance of general anaesthesia.
Fezolinetant (Veoza®) SMC number 2702 https://scottishmedicines.org.uk/media/8525/fezolinetant-veoza-non-sub-final-july-2024-for-website.pdf	**Indication under review:** treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.
Pegcetacoplan (Aspaveli®) SMC number 2715 https://scottishmedicines.org.uk/media/8571/pegcetacoplan-aspaveli-non-sub-final-august-2024-for-website.pdf	**Indication under review:** as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia
Volanesorsen (Waylivra®) SMC number 2716 https://scottishmedicines.org.uk/media/8573/volanosorsen-waylivra-non-sub-final-august-2024-for-website.pdf	**Indication under review:** as an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate.
Zilucoplan (Zilbrysq®) SMC number 2717 https://scottishmedicines.org.uk/media/8574/zilucoplan-zilbrysq-non-sub-final-august-2024-for-website.pdf	**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) antibody positive.

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 Amendment

Opiate brand changes

Fentanyl – Matrifen to Opiodur patches
Oxycodone – Longtec to Oxypro tablets
Buprenorphine – Butec to Sevodyne patches
Tapendatol – Palexia SR to Tadomon tablets

Formulary Deletions

Brand removal from formulary

- Dovobet gel and ointment
- Ganfort eye drops
- Ovestin cream

All the above generic products will remain on 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