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

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

West of Scotland Formulary Development

Work is currently underway to develop a new regional formulary for the 5 Health Boards across the West of Scotland, including NHS Forth Valley. Expert groups are shaping the first chapters, with additional chapters planned. A new digital platform will support condition-based prescribing, facilitating easier access to formulary choices aligned with patient treatment pathways. A new Regional Formulary Committee has recently been established which will support ongoing formulary decisions and chapter development. For detailed information on the development of formulary chapters, the involvement of members in expert working groups, and the indicative timelines for each chapter's development, please use the following link.

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

Medicines 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
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	**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
Maralixibat (Livmarli®) SMC2806	**Indication under review:** treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older. SMC restriction: for use in patients whose condition has	**Category 6 –** Not routinely available as local implementation plans are being developed or the	**Category 5 -** Not routinely available as local clinical experts do not wish to add the	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**
	not responded to standard of care medicines.	ADTC is waiting for further advice from local clinical experts	medicine to the formulary at this time or there is a local preference for alternative medicines	
Mercaptamine (Procysbi®) SMC2824	**Indication under review:** treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure. A phase III, open-label, crossover study demonstrated that extended-release mercaptamine (Procysbi®) was non-inferior to immediate-release mercaptamine in control of white blood cell cystine levels in patients with nephropathic cystinosis who were previously controlled on mercaptamine 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 at this time or there is a local preference for alternative medicines	N/A
Abaloparatide (Eladynos®) SMC 2764	**Indication under review:** treatment of osteoporosis in postmenopausal women at increased risk of fracture. **SMC restriction:** postmenopausal people with osteoporosis at very high risk of fracture, assessed using a validated fracture risk assessment tool.	**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
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 1 -** Available in line with national guidance	Secondary Care initiated and ongoing prescribing in Primary Care
Givinostat (Duvyzat®) SMC2856	**Indication under review:** treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. **SMC restriction:** Patients who are ambulant when they initiate	**Category 6 –** Not routinely available as local implementation plans are being developed or the	**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**
	givinostat treatment; this includes patients who are ambulant when they initiate givinostat and become non-ambulant during treatment. In a randomised, double-blind, phase III study, treatment with givinostat resulted in a statistically significant smaller decline in the four stairs climb time from baseline to month 18, compared with placebo.	ADTC is waiting for further advice from local clinical experts		
Progesterone soft vaginal capsules (Prometrium) SMC2869	**Indication under review:** the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages. Prometrium® is a licensed medicine replacing established off-label use of progesterone 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
Mirikizumab (Omvoh®) SMC 2822 ***(under consideration with the West of Scotland Chapter review)***	**Indication under review:** For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic 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**	Decision will be published by the West of Scotland Formulary Committee
Guselkumab solution for infusion and powder for injection (Tremfya®) SMC 2848 ***(under consideration with the West of Scotland Chapter review)***	**Indication under review:** 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, a biologic treatment, or a Janus kinase (JAK) inhibitor.	**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**	Decision will be published by the West of Scotland Formulary Committee

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Current / Previous Formulary decision**	**Updated FV Formulary position**	**Area of Prescribing**
Guselkumab solution for injection in pre-filled pen and concentrate for solution for infusion (Tremfya®) SMC2850 ***(under consideration with the West of Scotland Chapter review)***	**Indication under review:** For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic 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**	Decision will be published by the West of Scotland Formulary Committee
Budesonide suppository (Budenofalk®) SMC2855 ***(under consideration with the West of Scotland Chapter review)***	**Indication under review:** Short-term treatment of mild to moderate acute ulcerative colitis limited to the rectum (ulcerative proctitis) in adult patients.	**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**	Decision will be published by the West of Scotland Formulary Committee
Delgocitinib cream (Anzupgo) SMC2817 ***(under consideration with the West of Scotland Chapter review)***	**Indication under review:** treatment of moderate to severe chronic hand eczema (CHE) in adults for whom topical corticosteroids are inadequate or inappropriate.	**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**	Decision will be published by the West of Scotland Formulary Committee

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)	
Lecanemab (Leqembi®) SMC 2811	**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.
Fezolinetant (Veoza®) SMC 2798	**Indication under review:** for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.
Dupilumab (Dupixent®) SMC 2801	**Indication under review:** in adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate.
Letermovir (Prevymis®) SMC 2853	**Indication under review:** for prophylaxis of cytomegalovirus (CMV) disease in CMV-seronegative adults who have received a kidney transplant from a CMV-seropositive donor [D+/R-].
Melatonin prolonged-release tablets (Slenyto®) SMC2882	**Indication under review:** Treatment of insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been insufficient.
Iptacopan (Fabhalta®) SMC2889	**Indication under review:** treatment of adult patients with complement 3 glomerulopathy (C3G) in combination with a renin-angiotensin system (RAS) inhibitor, or in patients who are RAS-inhibitor intolerant, or for whom a RAS inhibitor is contraindicated.

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

Somapacitan (Sogroya®) - formulary has been updated to include ongoing prescribing in Primary Care now that a shared care agreement is in place.

Dapagliflozin is now marked 1st line.

Formulary Additions

Triamcinolone Acetonide (Intracinol) suspension 40mg/ml
Indication under review: Use to stain vitreous to allow effective removal (vitrectomy). Suspected or confirmed vitreous loss during intraocular surgery.
Category 2 - Available in line with local guidance **Secondary Care Only**

Formulary Deletions

Removal of **Pipexus** brand – Pramipexole is now listed generically

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