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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](http://www.scottishmedicines.org)

### Category Classification

#### Medicines Approved / Not Recommended By SMC

<b>Category 1</b>	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
<b>Category 2</b>	Available in line with local guidance for prescribing
<b>Category 3</b>	Available from a specialist centre in another NHS Board
<b>Category 4</b>	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
<b>Category 5</b>	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)
<b>Category 6</b>	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
<a href="#">Tirzepatide (Mounjaro®)</a> <a href="#">SMC number 2653</a>	<p><b>Indication under review:</b> 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 <math>\geq 30</math> kg/m<sup>2</sup> (obesity) or <math>\geq 27</math> kg/m<sup>2</sup> to <math>&lt; 30</math> kg/m<sup>2</sup> (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).</p> <p><b>SMC restriction:</b> for use in adults with BMI <math>\geq 30</math> kg/m<sup>2</sup>* and at least one weight-related comorbidity.</p> <p><i>*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.</i></p>	<p><b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p><b>Decision pending</b></p>	<p>Currently N/A until decision has been made</p>
<a href="#">Abaloparatide (Eladynos®)</a> SMC <a href="#">2764</a>	<p><b>Indication under review:</b> treatment of osteoporosis in postmenopausal women at increased risk of fracture.</p> <p><b>SMC restriction:</b> postmenopausal people with osteoporosis at very high risk of fracture, assessed using a validated fracture risk assessment tool.</p>	<p><b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p><b>Decision pending</b></p>	<p>Currently N/A until decision has been made</p>
<a href="#">Givinostat (Duvyzat®)</a> <a href="#">SMC2856</a>	<p><b>Indication under review:</b> treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. <b>SMC restriction:</b> Patients who are ambulant when they initiate 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.</p>	<p><b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p><b>Category 5</b> - 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</p>	<p>N/A</p>
<a href="#">Progesterone soft vaginal capsules (Prometrium)</a> <a href="#">SMC2869</a>	<p><b>Indication under review:</b> 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</p>	<p><b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for</p>	<p><b>Category 5</b> - Not routinely available as local clinical experts do not wish to add the medicine to the</p>	<p>N/A</p>

**ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS**

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
	medicine replacing established off-label use of progesterone for this indication.	further advice from local clinical experts	formulary at this time or there is a local preference for alternative medicines	
<a href="#">Exagamglogene autotemcel (Casgevy)</a> <a href="#">SMC2852</a>	<b>Indication under review:</b> For the treatment of sickle cell disease in patients 12 years of age and older with recurrent vaso-occlusive crises who have the $\beta^S/\beta^S$ , $\beta^S/\beta^+$ or $\beta^S/\beta^0$ genotype, for whom haematopoietic stem cell transplantation is appropriate and a human leukocyte antigen matched related haematopoietic stem cell donor is not available.	<b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	<b>Category 5</b> - 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
<a href="#">Marstacimab (Hypvavzi)</a> <a href="#">SMC2759</a>	<b>Indication under review:</b> For routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with: <ul style="list-style-type: none"> <li>• severe haemophilia A (congenital factor VIII deficiency, FVIII &lt; 1%) without factor VIII inhibitors, or</li> <li>• severe haemophilia B (congenital factor IX deficiency, FIX &lt; 1%) without factor IX inhibitors.</li> </ul>	<b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	<b>Category 5</b> - 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
<a href="#">Ciclosporin (Vevizye®)</a> <a href="#">SMC2873</a>	<b>Indication under review:</b> Treatment of moderate to severe dry eye disease (keratoconjunctivitis sicca) in adult patients, which has not improved despite treatment with tear substitutes.	<b>Category 6</b> – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	<b>Decision pending</b>	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)

<a href="#">Clascoterone (Winlevi®) SMC2894</a>	<b>Indication under review:</b> topical treatment of acne vulgaris in patients 12 years of age and older.
<a href="#">Dupilumab (Dupixent®) SMC2896</a>	<b>Indication under review:</b> treatment of chronic spontaneous urticaria (CSU) in patients aged 12 years and older whose disease is not adequately controlled with H1 antihistamine treatment.
<a href="#">Sotatercept (Winrevair®) SMC2831</a>	<b>Indication under review:</b> in combination with other pulmonary arterial hypertension (PAH) therapies, for the treatment of PAH in adult patients with WHO Functional Class (FC) II to III, to improve exercise capacity.  In a phase III study of patients with PAH with WHO FC II or III who were receiving stable background therapy, sotatercept significantly improved exercise capacity, measured by the 6-minute walk test, compared with placebo.
<a href="#">Zuranolone (Zurzuvae®) SMC2862</a>	<b>Indication under review:</b> treatment of moderate or severe postnatal depression (PND) in adults following childbirth.  In a double-blind, phase III study, zuranolone, compared with placebo, improved depression measured by 17-item Hamilton Rating Scale for Depression (HAM-D-17) in adults with severe PND.
<a href="#">Donanemab (Kisunla®) SMC2871</a>	<b>Indication under review:</b> 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.  In a randomised, double-blind, phase III study, donanemab reduced cognitive and functional decline associated with early Alzheimer's disease compared with placebo at 76 weeks.

## **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*<sup>®</sup> 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**

##### **Systane Balance eye drops**

**Indication** – Meibomian Gland Deficiency and other severe dry eye conditions.

Specialist initiation only, may be continued in Primary Care

#### **Formulary Deletions**

QV lotion

The formulary brand Alzest for Rivastigmine patches have been removed due to discontinuation. Rivastigmine patches are now listed generically.

Apraclonidine 5mg/ml 0.5% (Iopidine) have been removed due to discontinuation.

**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

