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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

The [West of Scotland Formulary website](#) is now live. A Regional Formulary Committee has 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	<p>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/m² (obesity) or ≥ 27 kg/m² to < 30 kg/m² (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>SMC restriction: for use in adults with BMI ≥ 30 kg/m²* 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>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>N/A</p>
Abaloparatide (Eladynos®) SMC 2764	<p>Indication under review: treatment of osteoporosis in postmenopausal women at increased risk of fracture.</p> <p>SMC restriction: postmenopausal people with osteoporosis at very high risk of fracture, assessed using a validated fracture risk assessment tool.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Currently N/A until decision has been made</p>
Ciclosporin (Vevizye®) SMC2873	<p>Indication under review: Treatment of moderate to severe dry eye disease (keratoconjunctivitis sicca) in adult patients, which has not improved despite treatment with tear substitutes.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>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</p>	<p>N/A</p>
Vanzacaftor/tezacaftor/deutivacaftor film-coated tablets (Alyftrek®) SMC2800	<p>Indication under review: For the treatment of cystic fibrosis (CF) in people aged 6 years and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Decision will be published by the West of Scotland Formulary Committee</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
Nemolizumab powder and solvent for solution for injection pre-filled pen (Nemluvio) SMC2833	<p>Indication under review: for the treatment of moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors in adults and adolescents 12 years and older with a body weight of at least 30 kg, who are candidates for systemic therapy. SMC restriction: for use in 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.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Decision will be published by the West of Scotland Formulary Committee</p>
Sotatercept powder and solvent for solution for injection (Winrevair) SMC2923	<p>Indication under review: 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. SMC restriction: for use in patients with intermediate-low risk status on the European Society of Cardiology (ESC)/European Respiratory Society (ERS) four-strata risk rating system.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Decision will be published by the West of Scotland Formulary Committee</p>
Budesonide (Kinpeygo) SMC2814	<p>Indication under review: treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥ 1.0 g/day (or urine protein-to-creatinine ratio ≥ 0.8 g/g*). *Equivalent to ≥ 90 mg/mmo</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Currently N/A until decision has been made</p>
Sparsentan film-coated tablet (Filspari) SMC2847	<p>Indication under review: treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥ 1.0 g/day or urine protein-creatinine ratio ≥ 0.75 g/g [85 mg/mmol].</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Currently N/A until decision has been made</p>
Capsaicin cutaneous patch (Qutenza) SMC2861	<p>Indication under review: treatment of peripheral neuropathic pain in adults either alone or in combination with other medicinal products for the treatment of pain.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p>Decision pending</p>	<p>Decision will be published by the West of Scotland Formulary Committee</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
Dupilumab 300 mg solution for injection in pre-filled pen and syringe (Dupixent) SMC2851	Indication under review: as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.	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
Semaglutide FlexTouch solution for injection in pre-filled pen (Wegovy) SMC2872	Indication under review: As an adjunct to a reduced-calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight (BMI ≥ 27 kg/m ²).	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)

Omaveloxolone (Skyclarys) SMC2845	Indication under review: For the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older
Zilucoplan (Zilbrysq) SMC2830	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.
Seladelpar (Livdelzi) SMC2899	Indication under review: For the treatment of primary biliary cholangitis (PBC), including pruritus, in adults in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA.
Baloxavir marboxil film-coated tablets (Xofluza) SMC2920	Indication under review: treatment of uncomplicated influenza in patients aged 3 weeks and above.
Baloxavir marboxil film-coated tablets (Xofluza) SMC2921	Indication under review: post-exposure prophylaxis of influenza in individuals aged 3 weeks and above.
Eszopiclone film-coated tablets (Lunivia) SMC2922	Indication under review: treatment of insomnia, in adults, usually for short-term duration.
Nemolizumab (Nemluvio) SMC2832	Indication under review: For the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy
Gefapixant (Lyfnua) SMC2926	Indication under review: In adults for the treatment of refractory or unexplained chronic cough.

Peginterferon alfa-2a (Pegasys) SMC2936	Indication under review: As monotherapy in adults for the treatment of polycythaemia vera.
Peginterferon alfa-2a (Pegasys) SMC2937	Indication under review: As monotherapy in adults for the treatment of essential thrombocythaemia.

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

- Melatonin indications have been added for both IR and MR tablets. Both are now first-line options, with additional detail included to explain why crushing MR tablets is unsuitable.
- Preferred brand of Methylphenidate XL is now **Atenza XL**

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

