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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 Sub Group 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://guidelines.staffnet.fv.scot.nhs.uk/pharmacy-and-prescribing/>

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.

<http://guidelines.staffnet.fv.scot.nhs.uk/>

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

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
NEUROLOGY			
Diroximel fumarate 231mg gastro-resistant hard capsules (Vumerity®) SMC Number 2444 https://www.scottishmedicines.org.uk/media/6672/diroximel-fumarate-vumerity-abbreviated-final-jan-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: treatment of adult patients with relapsing remitting multiple sclerosis.	Category 2 – available in line with local guidance for prescribing. Replaces Dimethyl fumarate as a formulary choice	Acute Services
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)			
Belimumab 120mg, 400mg powder for concentrate for solution for infusion and 200mg solution for injection in pre-filled pen (Benlysta®) SMC Number 2483 https://www.scottishmedicines.org.uk/media/6791/belimumab-benlysta-non-sub-final-march-2022-for-website.pdf	Indication under review: In combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis.		
Carfilzomib 10mg, 30mg and 60mg powder for solution for infusion (Kyprolis®) SMC Number 2484 https://www.scottishmedicines.org.uk/media/6792/carfilzomib-kyprolis-non-sub-final-march-2022-for-website.pdf	Indication under review: In combination with daratumumab and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.		
Ibrutinib 140mg, 280mg, 420mg and 560mg film-coated tablets (Imbruvica®) SMC Number 2485 https://www.scottishmedicines.org.uk/media/6794/ibrutinib-imbruvica-non-sub-march-2022-for-website.pdf	Indication under review: In combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia.		
Cemiplimab 350 mg concentrate for solution for infusion (Libtayo®) SMC Number 2489 https://www.scottishmedicines.org.uk/media/6860/cemiplimab-libtayo-non-sub-final-april-2022-for-website.pdf	Indication under review: As monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in $\geq 50\%$ tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: locally advanced NSCLC who are not candidates for definitive chemoradiation, or metastatic NSCLC		
Daratumumab 20mg/mL concentrate for solution for infusion and 1,800mg solution for injection (Darzalex®) SMC Number 2416 https://www.scottishmedicines.org.uk/media/6870/daratumumab-darzelex-final-april-2022-for-website.pdf	Indication under review: in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.		
Ibrutinib 140mg, 280mg, 420mg and 560mg film coated tablets (Imbruvica®) SMC Number 2485 https://www.scottishmedicines.org.uk/media/6794/ibrutinib-imbruvica-non-sub-march-2022-for-website.pdf	Indication under review: In combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia.		
Ixekizumab 80mg solution for injection in pre-filled syringe or pen (Taltz®) SMC Number 2440 https://www.scottishmedicines.org.uk/media/6932/ixekizumab-taltz-final-may-2022-for-website.pdf	Indication under review: Ankylosing spondyloarthritis (radiographic axial spondyloarthritis) Treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. Non-radiographic axial spondyloarthritis Treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).		

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
<p>Mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen and 100mg solution for injection in pre-filled syringe (Nucala®) SMC Number 2490 https://www.scottishmedicines.org.uk/media/6864/mepolizumab-nucala-egpa-non-sub-final-april-2022-for-website.pdf</p>		<p>Indication under review: As an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).</p>	
<p>Mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen and 100mg solution for injection in pre-filled syringe (Nucala®) SMC Number 2488 https://www.scottishmedicines.org.uk/media/6855/mepolizumab-nucala-hs-non-sub-final-april-2022-for-website.pdf</p>		<p>Indication under review: As add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause.</p>	
<p>Mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen and 100mg solution for injection in pre-filled syringe (Nucala®) SMC Number 2491 https://www.scottishmedicines.org.uk/media/6856/mepolizumab-nucala-scr-non-sub-final-april-2022-for-website.pdf</p>		<p>Indication under review: As an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control.</p>	
<p>Ropeginterferon alfa-2b 250 micrograms/0.5 mL solution for injection in pre-filled pen (Besremi®) SMC Number 2421 https://www.scottishmedicines.org.uk/media/6873/ropeginterferon-alfa-2b-besremi-final-april-2022-amended-040522-for-website.pdf</p>		<p>Indication under review: as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly.</p>	
<p>Ruxolitinib 5mg, 10mg, 15mg and 20mg tablets (Jakavi®) SMC Number 2498 https://www.scottishmedicines.org.uk/media/6929/ruxolitinib-jakavi-non-sub-final-may-2022-for-website.pdf</p>		<p>Indication under review: for the treatment of:</p> <ul style="list-style-type: none"> • patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids • patients aged 12 years and older with chronic graft versus host disease who have inadequate response to corticosteroids 	
<p>Tepotinib 225mg film-coated tablets (Tepmetko®) SMC Number 2457 https://www.scottishmedicines.org.uk/media/6930/tepotinib-tepmetko-final-may-2022-amended-070622-for-website.pdf</p>		<p>Indication under review: for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations.</p>	

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
<p>Bimekizumab 160mg solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®) SMC Number 2410 https://www.scottishmedicines.org.uk/media/6429/bimekizumab-bimzelx-abb-final-october-2021-for-website.pdf</p>	<p>Indication under review: treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.</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>Chloroprocaine hydrochloride 10mg/mL solution for injection (Ampres®) SMC Number 2373 https://www.scottishmedicines.org.uk/media/6333/chloroprocaine-hydrochloride-ampres-final-sept-2021-for-website.pdf</p>	<p>Indication under review: Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes. SMC restriction: for use in day-case anaesthetic pathways.</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 experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines</p>	<p align="center">Not applicable</p>
<p>Dupilumab 200mg and 300mg solution for injection in pre-filled syringe and pen (Dupixent®) SMC Number 2317 dupilumab-dupixent-final-march-2021-amended-190321-for-website.pdf scottishmedicines.org.uk</p>	<p>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</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 experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines</p>	<p align="center">Not applicable</p>
<p>Amikacin liposomal nebuliser dispersion 590mg (Arikayce®) SMC Number 2432 https://www.scottishmedicines.org.uk/media/6539/amikacin-arikayce-resub-final-november-2021-for-website.pdf</p>	<p>Indication under review: Treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.</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 experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines</p>	<p align="center">Not applicable</p>
<p>Empagliflozin 10mg film-coated tablets (Jardiance®) SMC Number 2396 https://www.scottishmedicines.org.uk/media/6334/e</p>	<p>Indication under review: in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for</p>	<p>Decision pending</p>	

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
mpagliflozin-jardiance-abbreviated-final-sept-2021-for-website.pdf		further advice from local clinical experts		
Tralokinumab 150mg solution for injection in pre-filled syringe (Adtralza®) SMC Number 2403 https://www.scottishmedicines.org.uk/media/6589/tralokinumab-adtralza-final-december-2021docx-for-website.pdf	Indication under review: treatment of moderate-to-severe atopic dermatitis in adult patients 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.	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	
Olopatadine hydrochloride 600 micrograms / mometasone furoate monohydrate 25 micrograms per actuation nasal spray (Ryaltris®) SMC Number 2418 https://www.scottishmedicines.org.uk/media/6536/olopatadine-hydrochloride_mometason-e-furoate-monohydrate-ryaltris-abb-final-nov-2021-for-website.pdf	Indication under review: in adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis. SMC restriction: for use where monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	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	
Midazolam 2mg/mL oral solution in single-dose container (Ozalin®) SMC Number 2392 https://www.scottishmedicines.org.uk/media/6337/midazolam-ozalin-abbreviated-final-sept-2021-for-website.pdf	Indication under review: in children from 6 months to 17 years old, for moderate sedation before a therapeutic or diagnostic procedure or as premedication before anaesthesia.	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 experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines	Not Applicable
Ponesimod titration pack and 20mg film-coated tablets (Ponvory®) SMC Number 2384 https://www.scottishmedicines.org.uk/media/6424/ponesimod-ponvory-abbreviated-final-october-2021-for-website.pdf	Indication under review: the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. SMC restriction: Adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features, suitable for or requesting an oral 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	Category 5 – Not routinely available as local experts do not wish to add the medicine to the formulary at this time or there is local preference for alternative medicines	Not Applicable

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 « Staff Net](#) or via the [Forth Valley Formulary](#) internet site <https://pharmacies.nhsforthvalley.com/local-guidance/forth-valley-formulary/>

Formulary Review

- **Combined oral contraceptives** – continue with the Consilient range of products.
- **Lucette[®] (ethinylestradiol/drospirone)(an alternative branded generic to Yasmin[®])** will **NOT** be added as a Formulary choice.
A Scriptswitch message will be added to remind GPs that the brand Yasmin[®] should not be prescribed as it is not approved by SMC and if ethinylestradiol/drospirone is required then it should be prescribed as the brand Lucette[®].
- **Copper IUD products** – preferred 1st and 2nd line choices amended to the most cost-effective choices.
- **Levonogestrel IUD's** – removed Jaydess[®] as this needs to be replaced after three years. Levosert[®] is 1st line and Kyleena[®] 2nd line.
- **Change from Vagifem[®] to Vagirux[®]** as the preferred estradiol vaginal tablets for vaginal atrophy.
Comment added regarding the preference to use estriol 0.1% cream (Ovestin[®]) rather than the 0.01% cream

Formulary addition

- **Ciprofloxacin/dexamethasone ear drops** - as per SMC advice. Initiation / recommendation by a specialist
- **Intranasal Naloxone (Nyxoid[®]) for Opioid overdose**
For use in specific patient groups when the IM formulation is unsuitable e.g. patients with needle phobia and would be used **2nd line**, intramuscular formulation will remain **1st line**.
The nasal spray to be prescribed by the substance use service
- **Dorzolamide with timolol P/F UDVs – change from Cosopt[®] brand to generic**

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

