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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
IMMUNOLOGY			
Bertralstat 150mg hard capsules (Orladeyo®) SMC Number 2405 berotralstat-oraldeyo-final-feb-2022-amended-220222-for-website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older. SMC restriction: patients who experience \geq two clinically significant attacks per month.	Category 3 - Available from a specialist centre in another NHS board	Acute services
NEUROLOGY			
Cannabidiol 100mg/ml oral solution (Epidyolex®) SMC Number 2262 In Confidence (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Dravat syndrome, in conjunction with clobazam, for patients 2 years of age and older.	Category 1 - Available in line with national guidance	Acute services
Cannabidiol 100mg/ml oral solution (Epidyolex®) SMC Number 2263 In Confidence (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older.	Category 1 - Available in line with national guidance	Acute services
Cannabidiol 100mg/mL oral solution (Epidyolex®) SMC Number 2402 cannabidiol-epidyolex-final-jan-2022-amended-200122-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older.	Category 3 - Available from a specialist centre in another NHS board	Acute services
PAEDIATRICS			
Risdiplam 0.75mg/mL powder for oral solution (Evrysdi®) SMC Number 2401 risdiplam-evrysdi-final-jan-2022-amended-270122-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the treatment of 5q spinal muscular atrophy (SMA) in patients 2 months of age and older, with a clinical diagnosis of SMA type 1, type 2 or type 3 or with one to four SMN2 [survival of motor neuron 2] copies.	Category 3 - Available from a specialist centre in another NHS board	Acute services – specialist services
ONCOLOGY – The following drugs are all currently classified as category 6 for the indications stated i.e. 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		
Enzalutamide 40mg film-coated tablets (Xtandi®) SMC Number 2400 In Confidence (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).		
Dostarlimab 500mg concentrate for solution for infusion (Jemperli®) SMC Number 2404 dostarlimab-jemperli-final-december-2021-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.		

Drug (approved by SMC)	SMC Advice
Lorlatinib 25mg and 100mg film-coated tablets (Lorviqua®) SMC Number 2415 06 March 2002 (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC Number 2385 nivolumab-opdivo-final-jan-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: in combination with ipilimumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM).
Pemigatinib 4.5mg, 9mg, and 13.5mg tablets (Pemazyre®) SMC Number 2399 pemigatinib-pemazyre-final-jan-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.
Sacituzumab govitecan 180mg powder for concentrate for solution for infusion (Trodelvy®) SMC Number 2446 sacituzumab-trodelvy-final-feb-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease.
Sotorasib 120mg film-coated tablets (Lumykras®) SMC Number 2443 sotorasib-lumykras-final-feb-2022-amended-220222-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: as monotherapy for the treatment of adult patients with KRAS G12C-mutated, locally advanced or metastatic, non-small cell lung cancer (NSCLC), who have progressed on, or are intolerant to platinum-based chemotherapy and/or anti PD-1/PD-L1 immunotherapy.
Tucatinib 50mg and 150mg film-coated tablets (Tukysa®) SMC Number 2398 tucatinib-tukysa-final-december-2021docx-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive locally advanced or metastatic breast cancer who have received at least two prior anti-HER2 treatment regimens.
Venetoclax 10mg, 50mg and 100mg tablets (Venclyxto®) SMC Number 2412 venetoclax-venclyxto-final-march-2022-for-website-amended-110422.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland Indication under review: in combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.
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)	
Standardised allergen extract of pollen from white birch betula verrucosa oral lyophilisate (Itulazax 12 SQ-Bet®) SMC Number 2471 In Confidence (scottishmedicines.org.uk)	Indication under review: In adult patients for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. ITULAZAX is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE).
Blinatumomab 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®) SMC Number 2468 In Confidence (scottishmedicines.org.uk)	Indication under review: As monotherapy for the treatment of adults with CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). Patients with Philadelphia chromosome positive B-precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.
Daratumumab 1,800 mg solution for injection (Darzalex®) SMC Number 2469 In Confidence (scottishmedicines.org.uk)	Indication under review: In combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy.

<p>Eculizumab 300mg concentrate for solution for infusion (Soliris®) SMC Number 2456 In Confidence (scottishmedicines.org.uk)</p>	<p>Indication under review: Treatment of adults with neuromyelitis optica spectrum disorder in patients who are anti-aquaporin-4 antibody-positive with a relapsing course of the disease.</p>
<p>Givosiran 189mg/mL solution for injection (Givlaari®) SMC Number 2470 In Confidence (scottishmedicines.org.uk)</p>	<p>Indication under review: Treatment of acute hepatic porphyria in adults and adolescents aged 12 years and older.</p>
<p>Hydrocortisone modified-release 5mg, 10mg and 20mg hard capsules (Efmody®) SMC Number 2414 hydrocortisone-modified-release-efmody-final-feb-2022-for-website.pdf (scottishmedicines.org.uk)</p>	<p>Indication under review: treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults.</p>
<p>Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC Number 2397 nivolumab-opdivo-final-december-2021docx-for-website.pdf (scottishmedicines.org.uk)</p>	<p>Indication under review: in combination with ipilimumab and 2 cycles of platinum-based chemotherapy for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours have no sensitising EGFR mutation or ALK translocation.</p>
<p>Solriamfetol 75mg and 150mg film-coated tablets (Sunosi®) SMC Number 2419 In Confidence (scottishmedicines.org.uk)</p>	<p>Indication under review: to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP).</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>Budesonide 9mg prolonged release tablet (Cortiment®) SMC Number 2448 https://www.scottishmedicines.org.uk/media/6584/budesonide-cortiment-abbreviated-final-dec-2021docx-for-website.pdf</p>	<p>Indication under review: Induction of remission in patients with active microscopic colitis</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 1 - Available in line with national guidance</p>	
<p>Avatrombopag 20mg film-coated tablets (Doptelet®) SMC Number 2345 https://www.scottishmedicines.org.uk/media/6181/avatrombopag-doptelet-final-july-2021-for-website.pdf</p>	<p>Indication under review: Treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids or immunoglobulins). SMC restriction: to use in patients with severe symptomatic ITP or a high risk of bleeding.</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>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-abbreviated-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>	

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
<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>Decision pending</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>Decision pending</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>Decision pending</p>	
<p>Empagliflozin 10mg film-coated tablets (Jardiance®) SMC Number 2396 https://www.scottishmedicines.org.uk/media/6334/empagliflozin-jardiance-abbreviated-final-sept-2021-for-website.pdf</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 further advice from local clinical experts</p>	<p>Decision pending</p>	
<p>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</p>	<p>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.</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>	

ADTC DECISIONS PENDING/CHANGES FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
<p>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</p>	<p>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.</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>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</p>	<p>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.</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 still pending</p>	
<p>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</p>	<p>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.</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 still pending</p>	

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/>

No formulary changes were made for this edition of the Newsletter.

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

