



Edition: May 2024
Volume: 21 No:1

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 at the Pharmacy page on the Quality Improvement Website on the following link:

<https://staffnet.fv.scot.nhs.uk/guidelines/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.

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

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

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
Atogepant tablets (Aquipta®) SMC Number 2599 https://www.scottishmedicines.org.uk/media/7867/atogepant-aquipta-abb-final-sept-2023-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: for the prophylaxis of migraine in adults who have at least 4 migraine days per month. SMC restriction: for patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.	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
Avacopan capsules (Tavneos®) SMC Number 2578 https://www.scottishmedicines.org.uk/media/7938/avacopan-tavneos-final-oct-2023-for-website.pdf	Accepted for use within NHSScotland. Indication under review: In combination with a rituximab or cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).	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
Bimekizumab (Bimzelx®) SMC Number 2605 https://www.scottishmedicines.org.uk/media/7939/bimekizumab-bimzelx-abb-final-oct-2023-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). SMC restriction: Use in patients with active psoriatic arthritis who have not responded adequately to two conventional DMARDs, given either alone or in combination.	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Bimekizumab (Bimzelx®) SMC Number 2616 https://www.scottishmedicines.org.uk/media/7988/bimekizumab-bimzelx-abb-final-nov-2023-for-website.pdf	Accepted for use within NHSScotland. Indication under review: axial spondyloarthritis • For the treatment of adults 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 or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). • For the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional 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
Dapagliflozin film-coated tablets (Forxiga®) SMC Number 2577 https://www.scottishmedicines.org.uk/media/7757/dapagliflozin-forxiga-abb-final-july-2023-for-website.pdf	Accepted for use within NHSScotland. Indication under review: in adults for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) >40%.	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
Deucravacitinib film-coated tablets (Sotyktu®) SMC Number 2581 https://www.scottishmedicines.org.uk/media/7992/deucravacitinib-sotyktu-abb-final-oct-2023-for-website.pdf	Indication under review: for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: patients who have failed to respond to standard systemic therapies	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for	Category 5 – available in line with local guidance for prescribing.	For use in specialist services only

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
cravacitinib-sotyktu-final-nov-2023-amended-011223-for-website.pdf	(including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	further advice from local clinical experts		
Degarelix injection (Firmagon®) SMC Number 2625 https://www.scottishmedicines.org.uk/media/7991/degarelix-firmagon-abb-final-nov-2023-for-website.pdf	Accepted for use within NHSScotland. Indication under review: <ul style="list-style-type: none"> • for treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy. • as neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer 	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
Empagliflozin film-coated tablet (Jardiance®) SMC Number 2523 https://www.scottishmedicines.org.uk/media/7563/em-pagliflozin-jardiance-final-april-2023-for-website.pdf	Accepted for use within NHSScotland. Indication under review: in adults for the treatment of symptomatic chronic heart failure with preserved ejection fraction (left ventricular ejection fraction [LVEF] >40%).	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
Faricimab 120mg/mL solution for injection (Vabysmo®) SMC Number 2499 https://www.scottishmedicines.org.uk/media/7205/faricimab-vabysmo-final-oct-2022docxfor-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO) SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) of 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Fenfluramine oral solution (Fintepla®) SMC Number 2569 https://www.scottishmedicines.org.uk/media/8002/fenfluramine-fintepla-final-sept-2023-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: for the treatment of seizures associated with Dravet syndrome as an add-on to other anti-epileptic medicines for patients 2 years of age and older. SMC restriction: as add-on therapy for treating seizures associated with Dravet syndrome where seizures have not been controlled in people aged 2 years and older after trying two or more antiseizure medicines.	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	N/A
Foslevodopa-foscarbidopa 240mg/mL + 12mg/mL solution for infusion (Produodopa®) SMC Number 2574 https://www.scottishmedicines.org.uk/media/8162/foslevodopa-foscarbidopa-produodopa-abb-final-feb-2024-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. SMC restriction: for use in patients not eligible for deep brain stimulation (DBS).	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

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
<p>Galcanezumab 120mg solution for injection in prefilled pen (Emgality®) SMC Number 2313 https://www.scottishmedicines.org.uk/media/5872/galcanezumab-emgality-final-march-2021-amended-060421-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: prophylaxis of migraine in adults who have at least 4 migraine days per month. SMC restriction: for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive 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>Category 2 - Available in line with local guidance for prescribing</p>	<p>For use in specialist services only</p>
<p>Inclisiran (Leqvio®) SMC Number 2358 https://www.scottishmedicines.org.uk/media/6188/inclisiran-leqvio-final-july-2021-amended-050821-for-website.pdf</p>	<p>Accepted for use restricted use within NHSScotland. Indication under review: for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients who are unable to reach LDL-C goals with the maximum tolerated dose of a statin, or • alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated. SMC restriction: for specialist use only in patients at high cardiovascular risk as follows: • patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, • patients with HeFH and LDL-C≥3.5mmol/L, for secondary prevention of cardiovascular events or, • patients with high risk due to previous cardiovascular events and LDL-C≥4.0mmol/L or, • patients with recurrent/polyvascular disease and LDL-C≥3.5mmol/L.</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>To be prescribed by the FV Lipid Clinic and to be supplied via Homecare</p>
<p>Maribavir tablets (Livtency®) SMC Number 2576 https://www.scottishmedicines.org.uk/media/7863/maribavir-livtency-final-sept-2023-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). Consideration should be given to official guidance on the appropriate use of antiviral 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 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>
<p>Nirmatrelvir and ritonavir (Paxlovid®) SMC Number 2557 https://www.scottishmedicines.org.uk/media/7674/20230622-collaborative-advice-document-for-nicmta878-v30.pdf</p>	<p>Accepted for use restricted use within NHSScotland. Indication under review: Treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19</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 2 - Available in line with local guidance for prescribing</p>	<p>For use in specialist services only</p>
<p>Patiromer sorbitex calcium 8.4g and 16.8g powder for oral suspension</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: treatment of hyperkalaemia in adults. SMC restriction: in the emergency care</p>	<p>Category 6 – Not routinely available as local implementation plans are being developed or the</p>	<p>Category 5 - Not routinely available as local clinical experts do not wish to add 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
(Veltassa®) SMC Number 2568 https://www.scottishmedicines.org.uk/media/7508/patromer-veltassa-abbreviated-final-march-2023-amended-040423-for-website.pdf	setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.	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 <i>Local preference to use SZC (Lokelma®) for this indication</i>	
Rimegepant oral lyophilisate (Vydura®) SMC Number 2521 https://www.scottishmedicines.org.uk/media/7565/rimegepant-vydura-acute-final-april-2023docxfor-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: for the acute treatment of migraine with or without aura in adults. SMC restriction: for patients who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol.	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 2 - Available in line with local guidance for prescribing	Specialist Services and Primary Care
Risankizumab (Skyrizi®) SMC Number 2534 https://www.scottishmedicines.org.uk/media/7935/risankizumab-skyrizi-abb-final-dec-2022-updated-250923-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Semaglutide Flexitouch solution for injection pre-filled pen (Wegovy®) SMC Number 2497 https://www.scottishmedicines.org.uk/media/7864/semaglutide-wegovy-final-dec-2022-amended-010923-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of • ≥30kg/m ² (obesity), or • ≥27kg/m ² to SMC restriction: BMI of ≥30kg/m ² * in the presence of at least one weight-related comorbidity. Patients should be treated in a specialist weight management service. *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	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	N/A
Sotrovimab (Xevudy®) SMC Number 2557 https://www.scottishmedicines.org.uk/media/7674/20230622-collaborative-advice-document-for-nice-mta878-v30.pdf	Accepted for restricted use within NHSScotland. Indication under review: Treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection	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

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
Tafamidis capsules (Vyndaqel®) SMC Number 2585 https://www.scottishmedicines.org.uk/media/7937/tafamidis-vyndaqel-resub-final-oct-2023-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Tezepelumab solution for injection in pre-filled syringe (Tezspire®) SMC Number 2541 https://www.scottishmedicines.org.uk/media/7758/tezepelumab-tezspire-final-july-2023-amended-020823-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment. SMC restriction: in adults and adolescents 12 years and older who either (i) experienced at least three exacerbations in the previous year and are not receiving maintenance treatment with oral corticosteroids or (ii) have blood eosinophils ≥ 150 cells/microlitre and are receiving maintenance treatment with oral corticosteroids.	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
Tocilizumab (RoActemra®) 20mg/ml concentrate for solution for infusion SMC Number 2552 https://www.scottishmedicines.org.uk/media/7674/20230622-collaborative-advice-document-for-nice-mta878-v30.pdf	Accepted for use within NHSScotland. Indication under review: Treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation	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
Voclosporin capsules (Lupkynis®) SMC Number 2570 https://www.scottishmedicines.org.uk/media/7865/voclosporin-lupkynis-final-sept-2023-for-website.pdf	Accepted for use within NHSScotland Indication under review: in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Vutrisiran solution for injection in pre-filled syringe (Amvuttra®) SMC Number 2596 https://www.scottishmedicines.org.uk/media/7824/vutrisiran-amvuttra-abb-final-aug-2023-for-website-amended-2508.pdf	Accepted for use within NHSScotland. Indication under review: For the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.	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
Secukinumab (Cosentyx®) 150mg or 300mg solution for injection in pre-filled pen or pre-filled syringe SMC Number 2592	Accepted for use within NHSScotland. Indication under review: for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. SMC restriction: for use in adult patients with active moderate to severe HS for whom	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 2 - Available in line with local guidance for prescribing	For use in specialist services only

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
secukinumab-cosentyx-final-jan-2024-for-website.pdf (scottishmedicines.org.uk)	adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.			
Dupilumab 300mg solution for injection in pre-filled syringe or pre-filled pen (Dupixent®) SMC Number 2598 dupilumab-dupixent-final-jan-2024-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic 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	Decision pending	Currently N/A until decision has been made
Upadacitinib (Rinvoq®) SMC Number 2575 upadacitinib-rinvoq-abbreviated-final-may-2023-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent, or for whom such therapies are not advisable.	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Upadacitinib (Rinvoq®) SMC Number 2510 upadacitinib-rinvoq-uc-abbreviated-final-sept-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.	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 2 - Available in line with local guidance for prescribing	For use in specialist services only
Ozanimod (Zeposia®) SMC Number 2478 ozanimod-zeposia-final-sept-2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the 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 or a biologic agent.	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
Rimegepant Oral Lyophilisate (Vydura) SMC Number 2603 rimegepant-vydura-resub-final-august-2023-for-website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland Indication under review: for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month.	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
Mirikizumab (Omvo®) SMC Number 2650 mirikizumab-omvo-abbreviated-final-march-2024-for-website.pdf	Accepted for use within NHSScotland. Indication under review: For the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for	Category 5 - Not routinely available as local clinical experts do not wish to add the medicine to 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
website.pdf scottishmedicines.org.uk	<p>response to, or were intolerant to either conventional therapy or a biologic treatment.</p> <p>Mirikizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors.</p>	<p>further advice from local clinical experts</p>	<p>formulary at this time or there is a local preference for alternative medicines</p>	
<p>Dupilumab 200mg and 300mg solution for injection in pre-filled syringe and pen (Dupixent) SMC Number 2317</p> <p>dupilumab-dupixent-final-march-2021-amended-190321-for-website.pdf scottishmedicines.org.uk</p>	<p>Accepted for use within NHSScotland. 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.</p> <p>SMC restriction: for the treatment of patients with blood eosinophils ≥ 150 cells/microlitre</p> <p>and FeNO ≥ 25 parts per billion, and ≥ 4 exacerbations in the preceding year, who have</p> <p>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 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 align="center">N/A</p>
<p>Difelikefalin solution for injection (Kapruvia®) SMC Number 2623</p> <p>difelikefalin-kapruvia-final-jan-2024-for-website.pdf scottishmedicines.org.uk</p>	<p>Accepted for use within NHSScotland. Indication under review: treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.</p> <p>SMC restriction: for use in patients with an inadequate response to best supportive care for reducing itch. Difelikefalin, compared with placebo, improved itch for a greater proportion of patients with moderate-to-severe itch who were undergoing haemodialysis for end-stage renal disease.</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 align="center">N/A</p>
<p>Daridorexant (Quviviq®) SMC Number 2611</p> <p>daridorexant-quviviq-final-march-2024-for-website.pdf scottishmedicines.org.uk</p>	<p>Accepted for use within NHSScotland. Indication under review: treatment of adult patients with Indication under review: insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.</p> <p>SMC restriction: in patients who have</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 align="center">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
	<p>failed cognitive behavioural therapy for insomnia (CBT-I) or for whom CBT-I is unsuitable or unavailable. Daridorexant, compared with placebo, improved time to fall asleep and waking after sleep onset in adults with insomnia.</p>			
<p>ritlecitinib (Litfulo®) SMC Number 2610 ritlecitinib-litfulo-final-march-2024-for-website.pdf (scottishmedicines.org.uk)</p>	<p>Accepted for use within NHSScotland. Indication under review: For the treatment of severe alopecia areata in adults and adolescents 12 years of age and older. In a randomised, double-blind, phase IIb/III study in patients with severe alopecia areata, ritlecitinib was associated with statistically significant improvements in scalp hair regrowth versus placebo at week 24.</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>
<p>tirzepatide (Mounjaro®) SMC Number 2633 tirzepatide-mounjaro-final-march-2024-amended-020424-for-website.pdf (scottishmedicines.org.uk)</p>	<p>Accepted for use within NHSScotland. Indication under review: for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: •as monotherapy when metformin is considered inappropriate due to intolerance or contraindications •in addition to other medicinal products for the treatment of diabetes.</p> <p>SMC restriction: in addition to other oral anti-diabetic medicines as an option when glucagon-like peptide-1 (GLP-1) receptor agonists would be considered. In three phase III studies, tirzepatide demonstrated statistically significant reductions from baseline in HbA1c compared with a GLP-1 receptor agonist and two basal insulins.</p> <p>SMC cannot recommend the use of tirzepatide as monotherapy when metformin is considered inappropriate due to intolerance or contraindications as the company's submission related only to its use in addition to other medicinal products for the treatment of diabetes.</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>
<p>glycopyrronium/for moterol fumarate (Bevespi Aerosphere®) SMC Number 2652 glycopyrronium-formoterol-fumarate-bevespi-aerosphere-abb-final-march-2024-for-website.pdf (scottishmedicines.org.uk)</p>	<p>Indication under review: as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).</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 2 - Available in line with local guidance for prescribing</p>	<p>Specialist Services and Primary Care</p>

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)	
Axicabtagene ciloleucel dispersion for infusion (Yescarta®) SMC Number 2646 https://www.scottishmedicines.org.uk/media/8028/axicabtagene-ciloleucel-non-sub-final-dec-2023-for-website.pdf	Indication under review: Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy.
Aflibercept solution for injection in pre-filled syringe (Eylea®) SMC Number 2612 https://www.scottishmedicines.org.uk/media/7755/aflibercept-eylea-non-sub-final-july-2023-for-website.pdf	Indication under review: in preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 2+ or 3+) or AP-ROP (aggressive posterior ROP) disease.
Amivantmab concentrate for solution for infusion (Rybrent®) SMC Number 2638 https://www.scottishmedicines.org.uk/media/7987/amivantmab-rybrent-non-sub-final-nov-2023-for-website.pdf	Indication under review: as monotherapy for treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy.
Baricitinib film-coated tablets (Olumiant®) SMC Number 2572 https://www.scottishmedicines.org.uk/media/7756/baricitinib-olumiant-final-july-2023-for-website.pdf	Indication under review: for the treatment of severe alopecia areata in adult patients.
Belantamab mafodotin powder for concentrate for solution for infusion (Blenrep®) SMC Number 2597 https://www.scottishmedicines.org.uk/media/8029/belantamab-blenrep-final-dec-2023-for-website.pdf	Indication under review: as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.
Crizotinib hard capsules (Xalkori®) SMC Number 2621 https://www.scottishmedicines.org.uk/media/7816/crizotinib-xalkori-non-sub-final-august-2023-for-website.pdf	Indication under review: as monotherapy for the treatment of paediatric patients (age ≥6 to <18 years) with: <ul style="list-style-type: none"> relapsed or refractory systemic anaplastic lymphoma kinase (ALK) positive anaplastic large cell lymphoma (ALCL) recurrent or refractory anaplastic lymphoma kinase (ALK) positive unresectable inflammatory myofibroblastic tumour (IMT).
Dermatophagoides pteronyssinus and Dermatophagoides farinae oral lyophilisate (Acarizax®) SMC Number 2613 https://www.scottishmedicines.org.uk/media/7752/dermatophagoides-acarizax-non-sub-final-july-2023-for-website.pdf	Indication under review: <ul style="list-style-type: none"> •Adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with at least one of the following conditions: <ul style="list-style-type: none"> ○ persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication ○ house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment. •Adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.
Efgartigimod alfa concentrate solution for infusion (Vyvgart®) SMC Number 2561 https://www.scottishmedicines.org.uk/media/7931/efgartigimod-alfa-vyvgart-final-oct-2023-amended-251023-for-website.pdf	Indication under review: as an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive
Lumasiran solution for injection (Oxlumo®) SMC Number 2639 https://www.scottishmedicines.org.uk/media/7993/lumasiran-oxlumo-non-sub-final-nov-2023-for-website.pdf	Indication under review: Treatment of primary hyperoxaluria type 1 (PH1) in all age groups
Mercaptamine capsules (Procsybi®) SMC Number 2571 https://www.scottishmedicines.org.uk/media/7932/mercaptamine-procsybi-resub-final-oct-2023-amended-031123-for-website.pdf	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.
Mosunetuzumab concentrate for solution for	Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least

infusion (Lunsumio®) SMC Number 2542 https://www.scottishmedicines.org.uk/media/7819/mosunetuzu-mab-lunsumio-final-august-2023-for-website.pdf	two prior systemic therapies.
Osilodrostat tablets (Isturisa®) SMC Number 2640 https://www.scottishmedicines.org.uk/media/7995/osilodrostat-isturisa-non-sub-final-nov-2023-for-website.pdf	Indication under review: treatment of endogenous Cushing's syndrome in adult
Pegunigalsidase alfa concentrate solution for infusion (Elfabrio®) SMC Number 2591 https://www.scottishmedicines.org.uk/media/7933/pegunigalsidase-alfa-elfabrio-final-oct-2023-amended-111023-261023-for-website.pdf	Indication Under Review: for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry Disease (deficiency of alpha-galactosidase).
Progesterone vaginal capsules (Utrogestan®) SMC Number 2630 https://www.scottishmedicines.org.uk/media/7934/progesterone-vaginal-capsules-utrogestan-non-sub-final-oct-2023-for-website.pdf	Indication under review: Prevention of preterm birth in women with a singleton pregnancy who have a short cervix (mid-trimester sonographic cervix ≤ 25 mm) and/or a history of spontaneous preterm birth.
Ravulizumab concentrate for solution for infusion (Ultomiris®) SMC Number 2657 https://www.scottishmedicines.org.uk/media/8104/ravulizumab-ultomiris-gmg-non-sub-final-jan-2024-for-website.pdf	Indication under review: as an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.
Ravulizumab concentrate for solution for infusion (Ultomiris®) SMC Number 2658 https://www.scottishmedicines.org.uk/media/8105/ravulizumab-ultomiris-nmosd-non-sub-final-jan-2024-for-website.pdf	Indication under review: treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.
Ropeginterferon alfa-2b solution for injection in pre-filled pen (Besremi®) SMC Number 2563 https://www.scottishmedicines.org.uk/media/7704/ropeginterferon-alfa-2b-besremi-resub-final-june-2023-for-website.pdf	Indication under review: as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly.
Selumetinib hard capsules (Koselugo®) SMC Number 2540 https://www.scottishmedicines.org.uk/media/7754/selumetinib-koselugo-final-july-2023-for-website.pdf	Indication Under Review: as monotherapy for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above.
Setmelanotide 10mg/ml solution for injection (Imcivree®) SMC Number 2565 https://www.scottishmedicines.org.uk/media/7358/setmelanotide-imcivree-non-sub-final-dec-2022-for-website.pdf	Indication under review: Treatment of obesity and the control of hunger associated with genetically confirmed Bardet-Biedl syndrome (BBS) in adults and children 6 years of age and above.
Tixagevimab plus cilgavimab for preventing COVID-19 SMC Number 2580 https://www.scottishmedicines.org.uk/media/7620/20230614-collaborative-advice-document-for-ta900-tixagevimab-plus-cilgavimab-v10.pdf	Indication below: Pre-exposure prophylaxis of COVID-19 in adults who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and: <ul style="list-style-type: none"> • who are unlikely to mount an adequate immune response to COVID-19 vaccination or • for whom COVID-19 vaccination is not recommended. Not recommended for use within NHSScotland
Pitolisant (Wakix®) SMC Number 2662 scottishmedicines.org.uk	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, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP).
Satralizumab (Enspryng®) SMC Number 2663 scottishmedicines.org.uk	Indication under review: As a monotherapy or in combination with immunosuppressive therapy (IST) for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in adult and adolescent patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive.

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 <https://pharmacies.nhsforthvalley.com/local-guidance/forth-valley-formulary/>

Formulary Additions

- Optifibre
- Semaglutide (Rybelsus®)
- Fortisip 2KCAL
- Fortisip Compact Protein
- Vital 1.5 KCAL
- Fortisip Plant based (new product)
- Aymes Actasolve Smoothie
- Nutilis Complete Drink Level 3
- Apixaban tablets

Formulary Amendment

- Adacal D3 Effervescent tablets – calcium/vitamin D formulation for patients with swallowing difficulties with caplets/tablets. Replaces Calfovit D3 sachets which have been discontinued.

Formulary Deletions – ONS

- Fortisip Yoghurt Style
- Vitasavory

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

