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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 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
<p>Belimumab 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) SMC Number 2477 https://www.scottishmedicines.org.uk/media/7202/belimumab-benlysta-final-oct-2022docxfor-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: Add-on therapy in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥ 10.</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>Hospital use only</p>
<p>Belimumab 200mg solution for injection in pre-filled pen or pre-filled syringe (Benlysta®) SMC Number 2530 https://www.scottishmedicines.org.uk/media/7237/belimumab-benlysta-abb-final-oct-2022docxfor-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥ 10.</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>Hospital use only</p>
<p>Brolucizumab 120mg/mL solution for injection and solution for injection in pre-filled syringe (Beovu®) SMC Number 2508 brolucizumab-beovu-abb-final-sept-2022-for-website.pdf scottishmedicines.org.uk</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: in adults for the treatment of visual impairment due to diabetic macular oedema. SMC restriction: treatment of visual impairment due to diabetic macular oedema in adults with best corrected visual acuity 75 Early Treatment Diabetic Retinopathy Study letters or less at baseline.</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 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>Budesonide 1mg orodispersible tablets (Jorveza®) SMC Number 2158 https://www.scottishmedicines.org.uk/media/5460/budesonide-jorveza-final-september-2020-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: Treatment of eosinophilic oesophagitis (EoE) in adults (older than 18 years of age). SMC restriction: For patients unsuccessfully treated with proton pump inhibitors. Submitted Proforma</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>Specialist Initiation and continued in Primary Care</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
Buprenorphine/naloxone 1.4mg/0.36mg, 2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg, 11.4mg/2.9mg sublingual tablets (Zubsolv®) SMC Number 2123 https://www.scottishmedicines.org.uk/media/7203/buprenorphine-naloxone-zubsolv-abb-final-nov-2018-amended-29922docxfor-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. SMC restriction: for use in patients for whom methadone is not suitable.	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 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
Bulevirtide 2mg powder for solution for injection (Hepcludex®) SMC Number 2520 https://www.scottishmedicines.org.uk/media/7451/bulevirtide-hepcludex-final-feb-2023-for-website.pdf	Accepted for restricted use within NHSScotland. Indication Under Review: for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease. SMC restriction: to use in patients with evidence of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based	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	
Delta-9-tetrahydrocannabinol 2.7mg and cannabidiol 2.5mg per 100 microlitre spray (Sativex® Oromucosal Spray) SMC Number 2473 https://www.scottishmedicines.org.uk/media/7097/delta-9-tetrahydrocannabinol-sativex-final-aug-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: As treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of 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 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 10mg film-coated tablets (Jardiance®) SMC Number 2396 https://www.scottishmedicines.org.uk/media/6334/em-pagliflozin-jardiance-abbreviated-final-sept-2021-for-website.pdf	Accepted for use within NHSScotland. Indication under review: in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.	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 1 – in line with national guidance	Initiated/recommended by heart failure specialists and then continued in primary care as per local guidance.
Eptinezumab 100mg concentrate for solution for infusion (Vyepti®) SMC Number 2547 https://www.scottishmedicines.org.uk/media/7403/eptinezumab-vyepti-abb-final-jan-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	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for	Category 5 – not routinely available as clinical experts do not wish to add the medicine to the formulary at this time or there is	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
	have had prior failure on three or more migraine preventive treatments.	further advice from local clinical experts	a local preference for alternative medicines	
Estradiol 1mg / micronised progesterone 100mg capsules (Bijuve®) SMC Number 2502 https://www.scottishmedicines.org.uk/media/7098/estradiol-micronised-progesterone-bijuve-abb-final-aug-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited	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	
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	Decision Pending	
Faricimab 120mg/mL solution for injection (Vabysmo®) SMC Number 2512 https://www.scottishmedicines.org.uk/media/7293/faricimab-vabysmo-abb-final-nov-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD).	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
Finerenone 10mg and 20mg film-coated tablets (Kerendia®) SMC Number 2486 https://www.scottishmedicines.org.uk/media/7206/finerenone-kerendia-final-oct-2022docxfor-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.	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 1 – available in line with national guidance.	Specialist initiation and continued in primary care Once the patient has been stabilised on treatment for the first 4 months and monitoring been undertaken, treatment can be continued in primary care.

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
Levofloxacin 5mg/mL plus dexamethasone 1mg/mL eye drops solution (Ducressa®) SMC Number 2511 https://www.scottishmedicines.org.uk/media/7207/levofloxacin-dexamethasone-ducressa-abb-final-oct-2022docxfor-website.pdf	Accepted for use within NHSScotland. Indication under review: for prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents	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 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
Micronised progesterone 100mg capsules (Utrogestan®) SMC Number 2529 https://www.scottishmedicines.org.uk/media/7294/micronised-progesterone-utrogestan-abb-final-nov-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT).	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 1 – available in line with national guidance.	For prescribing in both secondary and primary care.
Nintedanib soft capsules (Ofev®) SMC Number 2513 https://www.scottishmedicines.org.uk/media/7449/nintedanib-ofev-resub-final-feb-2023-for-website.pdf	Accepted for restricted use within NHSScotland. Indication Under Review: in adults for the treatment of idiopathic pulmonary fibrosis (IPF). SMC Restriction: For use in patients with a predicted forced vital capacity (FVC) >80%	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	
Ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia®) SMC Number 2478 https://www.scottishmedicines.org.uk/media/7041/roxadustat-evrenzo-final-july-2022-for-website.pdf	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	
Roxadustat 20mg, 50mg, 70mg, 100mg and 150mg film-coated tablets (Evrenzo®) SMC 2461 https://www.scottishmedicines.org.uk/media/7041/roxadustat-evrenzo-final-july-2022-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD). SMC restriction: for use in patients who are non-dialysis dependent (NDD) at the time of treatment initiation.	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 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
Sodium zirconium cyclosilicate 10g powder for oral suspension (Lokelma®)	Accepted for restricted use within NHSScotland. Indication under review: for the treatment of hyperkalaemia in adult patients	Category 6 – Not routinely available as local implementation plans are being	Decision Pending	

ADTC DECISIONS/PENDING FOR SMC APPROVED DRUGS

Drug (approved by SMC)	SMC Advice	Current / Previous Formulary decision	Updated FV Formulary position	Area of Prescribing
SMC Number 2515 https://www.scottishmedicines.org.uk/media/7208/so-dium-zirconium-lokelma-abb-final-oct-2022docxfor-website.pdf	SMC restriction: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.	developed or the ADTC is waiting for further advice from local clinical experts		
Somatrogon 24mg and 60mg solution for injection in pre-filled pen (Ngenla®) SMC Number 2493 https://www.scottishmedicines.org.uk/media/7042/so-matrogon-ngenla-abb-final-july-2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone	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	
Trifarotene 50 microgram/g cream (Aklief®) SMC Number 2441 https://www.scottishmedicines.org.uk/media/7093/trif-arotene-aklief-abbreviated-final-jan-2022-amended-130722-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.	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 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
Tofacitinib 5mg film-coated tablets (Xeljanz®) SMC Number 2463 https://www.scottishmedicines.org.uk/media/7092/tofacitinib-xeljanz-final-aug-2022-amended-070922-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately 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 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
Upadacitinib 15mg, 30mg, and 45mg prolonged-release tablets (Rinvoq®) SMC Number 2510 upadacitinib-rinvoq-uc-abb-final-sept-2022-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, 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		
Upadacitinib 15mg prolonged-release tablet (Rinvoq®) SMC Number 2480 https://www.scottishmedicines.org.uk/media/7209/upadacitinib-rinvoq-final-oct-2022docxfor-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of active ankylosing spondylitis (AS) in adult patients who have responded inadequately 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 clinical experts do not wish to add the medicine to the formulary at this time or there is a local	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
			preference for alternative medicines	
<p>Upadacitinib 15mg prolonged-release tablets (Rinvoq®) SMC Number 2495 https://www.scottishmedicines.org.uk/media/7295/upadacitinib-rinvoq-resub-final-nov-2022-amended-081222-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Upadacitinib may be used as monotherapy or in combination with methotrexate. SMC restriction: in adults with moderate disease (a disease activity score [DAS28] of 3.2 to 5.1) when intensive therapy with 2 or more conventional DMARDs has not controlled the disease well enough. In a phase III randomised, placebo-controlled and active comparator study in patients who had an inadequate response to methotrexate, upadacitinib significantly improved the signs and symptoms of RA compared with placebo.</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>Upadacitinib 15mg prolonged-release tablets (Rinvoq®) SMC Number 2532 https://www.scottishmedicines.org.uk/media/7407/upadacitinib-rinvoq-nr-axs-pa-abb-final-jan-2023-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: for the treatment of active non-radiographic axial spondyloarthritis in adult patients 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).</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>	

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)

<p>Alpelisib 50mg, 150mg, 200mg film-coated tablets (Piqray®) SMC Number 2481 https://www.scottishmedicines.org.uk/search/?keywords=alpelisib</p>	<p>Indication under review: in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine-based therapy.</p>
<p>Darolutamide 300mg film-coated tablets (Nubeqa®) SMC Number 2544 https://www.scottishmedicines.org.uk/media/7507/darolutamide-nubeqa-final-march-2023-amended-20032023-for-website.pdf</p>	<p>Indication under review: treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.</p>
<p>Esketamine 28mg nasal spray, solution (Spravato®) SMC Number 2539 https://www.scottishmedicines.org.uk/media/7204/esketamine-spravato-non-sub-final-oct-2022docxfor-website.pdf</p>	<p>Indication under review: Co-administered with oral antidepressant therapy, in adults with a moderate to severe episode of Major Depressive Disorder, as acute short-term</p>

	treatment, for the rapid reduction of depressive symptoms, which according to clinical judgement constitute a psychiatric emergency.
Estetrol 14.2mg / drospirenone 3mg film-coated tablets (Drovelis®) SMC Number 2564 https://www.scottishmedicines.org.uk/media/7355/estetrol-drovelis-non-sub-final-dec-2022-for-website.pdf	Indication under review: Oral contraception.
Ferric maltol 30mg hard capsules (Feraccru®) SMC Number 2500 https://www.scottishmedicines.org.uk/media/7361/ferric-maltol-feraccru-resub-final-dec-2022-updated-12123-for-website.pdf	Indication under review: in adults for the treatment of iron deficiency.
Rimegepant oral lyophilisate (Vydura®) SMC Number 2567	Indication under review: for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month.
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 loss-of-function biallelic pro-opiomelanocortin (POMC), including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 6 years of age and above.
Tebentafusp 200 micrograms/mL concentrate for solution for infusion (Kimmtrak®) SMC Number 2549	Indication Under Review: as monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.
Tisagenlecleucel 1.2 x 10⁶ – 6 x 10⁸ cells dispersion for infusion (Kymriah®) SMC Number 2566 https://www.scottishmedicines.org.uk/media/7360/tisagenlecleucel-kymriah-non-sub-final-dec-2022-for-website.pdf	Indication under review: Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.
Venetoclax 10mg, 50mg and 100mg film-coated tablets (Venclyxto®) SMC Number 2509 https://www.scottishmedicines.org.uk/media/7210/venetoclax-venclyxto-non-sub-final-oct-2022docxfor-website.pdf	Indication under review: In combination with low-dose cytarabine for the treatment of adult patients with newly-diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.

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

- **Actimorph®** – for use in palliative care patients where liquid morphine is considered unsuitable.

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



