Edition: January 2022
Volume: 19 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 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-precribing/

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
ANAESTHETICS			
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	**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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
CARDIOLOGY			
Inclisiran 284mg solution for injection in pre-filled syringe (Leqvio®) SMC Number 2358 https://www.scottishmedicines.org.uk/media/6188/inclisiran-leqvio-final-july-2021-amended-050821-for-website.pdf	**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.	**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	
Bempedoic acid 180mg film-coated tablets (Nilemdo®) SMC Number 2363 https://www.scottishmedicines.org.uk/media/6104/bempedoic-acid-nilemdo-resubmission-final-june-2021-for-website.pdf **Bempedoic acid 180mg/ezetimibe 10mg film-coated tablets SMC Number 2406** https://www.scottishmedicines.org.uk/media/6330/bempedoic-acid-ezetimibe-nustendi-abbreviated-final-sept-2021-for-website.pdf	**Indication under review:** in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (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 contra-indicated. **SMC restriction:** for use in combination with ezetimibe in patients who are: • statin intolerant or for whom a statin is contra-indicated: and • where ezetimibe alone does not appropriately control LDL-C: and where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate	**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	

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
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	**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	
DERMATOLOGY			
5-aminolevulinic acid 8mg medicated plaster (Alacare®) SMC Number 2353 https://www.scottishmedicines.org.uk/media/6028/5-aminolevulinic-acid-alacare-abbreviated-final-may-2021-for-website.pdf	**Indication under review:** Single use treatment of mild actinic keratoses lesions with a maximum diameter of 1.8 cm on the face and scalp (hairless areas).	**Category 1 –** available in line with national guidance.	Acute Specialist Services
Baricitinib 2mg and 4mg film-coated tablets (Olumiant®) SMC Number 2337 https://www.scottishmedicines.org.uk/media/6030/baricitinib-olumiant-final-may-2021-for-website.pdf	**Indication under review:** for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy. **SMC restriction:** treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy who have failed at least one current systemic immunosuppressant due to intolerance, contraindication or inadequate disease control.	**Category 2** Available in line with local guidance for prescribing	Acute Specialist Services
Bimekizumab 160mg solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®) SMC Number 2410 https://www.scottishmedicines.org.uk/media/6429/bimekizumab-bimzelx-abb-final-october-2021-for-website.pdf	**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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
Tirbanibulin 10mg/g ointment (Klisyri®) SMC Number 2395 https://www.scottishmedicines.org.uk/media/6538/tirbanibulin-klisyri-final-november-2021-for-website.pdf	**Indication under review:** field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.	**Category 1 –** available in line with national guidance.	Acute Specialist Services Primary Care
Tralokinumab 150mg solution for injection in pre-filled syringe (Adtralza®) SMC Number 2403 https://www.scottishmedicines.org.uk/media/6589/tralokinumab-adtralza-final-december-2021docx-for-website.pdf	**Indication under review:** treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. **SMC restriction:** patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
ENT			
Olopatadine hydrochloride 600 micrograms / mometasone furoate monohydrate 25 micrograms per actuation nasal spray (Ryaltris®) SMC Number 2418 https://www.scottishmedicines.org.uk/media/6536/olopatad	**Indication under review:** in adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis. **SMC restriction**: for use where monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	

ine-hydrochloride_mometasone-furoate-monohydrate-ryaltris-abb-final-nov-2021-for-website.pdf			
Drug (approved by SMC)	**SMC Advice**	**New Drugs Sub-group Outcome**	**Area of Prescribing**
GASTROENTEROLOGY			
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	**Indication under review:** Induction of remission in patients with active microscopic colitis	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
HAEMATOLOGY			
Avatrombopag 20mg film-coated tablets (Doptelet®) SMC Number 2345 https://www.scottishmedicines.org.uk/media/6181/avatrombopag-doptelet-final-july-2021-for-website.pdf	**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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
HIV			
Cabotegravir 600mg prolonged-release suspension for injection (Vocabria®) SMC Number 2376 https://www.scottishmedicines.org.uk/media/6493/cabotegravir-vocabria-final-sept-2021-amended-241121-for-website.pdf	**Indication under review: i**n combination with rilpivirine prolonged-release injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class	**Category 1** Available in line with national guidance	Acute Specialist Services
NEUROLOGY			
Ofatumumab 20mg/0.4mL solution for injection in pre-filled syringe/pen (Kesimpta®) SMC Number 2357 https://www.scottishmedicines.org.uk/media/6108/ofatumumab-kesimpta-final-june-2021-for-website.pdf	**Indication under review:** treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. **SMC restriction:** treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.	**Category 2** Available in line with local guidance for prescribing	Acute Specialist Services
Opicapone 50mg hard capsules (Ongentys®) SMC Number 2430 https://www.scottishmedicines.org.uk/media/6587/opicapone-ongentys-abbreviated-final-dec-2021docx-for-website.pdf	**Indication under review:** as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.	**Category 2** Available in line with local guidance for prescribing	Acute Specialist Services initiation then continued in Primary Care

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Ponesimod titration pack and 20mg film-coated tablets (Ponvory®) SMC Number 2384 https://www.scottishmedicines.org.uk/media/6424/ponesimod-ponvory-abbrevaited-final-october-2021-for-website.pdf	**Indication under review:** the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. **SMC restriction:** Adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features, suitable for or requesting an oral treatment.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
PAEDIATRICS			
Vigabatrin 100mg and 500mg soluble tablets (Kigabeq®) SMC Number 2352 https://www.scottishmedicines.org.uk/media/6027/vigabatrin-kigabeq-abbreviated-final-may-2021-for-website.pdf	**Indication under review**: In infants and children from 1 month to less than 7 years of age for: -Treatment in monotherapy of infantile spasms (West's syndrome). medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated. **SMC restriction**: patients in whom other formulations of vigabatrin are not suitable.	**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	
Midazolam 2mg/mL oral solution in single-dose container (Ozalin®) SMC Number 2392 https://www.scottishmedicines.org.uk/media/6337/midazolam-ozalin-abbreviated-final-sept-2021-for-website.pdf	**Indication under review:** in children from 6 months to 17 years old, for moderate sedation before a therapeutic or diagnostic procedure or as premedication before anaesthesia.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
RENAL			
Ravulizumab 300mg/3ml and 1,100mg/11ml concentrate for solution for infusion (Ultomiris®) SMC Number 2330 ravulizumab-ultomiris-ahus-final-april-2021docx-for-website.pdf (scottishmedicines.org.uk)	**Indication under review:** for the treatment of patients with a body weight of 10kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab. **SMC restriction:** under the advice of the national renal complement therapeutics service	**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	
Sodium zirconium cyclosilicate 5g and 10g powder for oral suspension (Lokelma®) SMC Number 2288 https://www.scottishmedicines.org.uk/media/5371/sodium-zirconium-cyclosilicate-lokelma-final-august-2020docx-for-website.pdf	**Indication under review:** treatment of hyperkalaemia in adult patients. **SMC restriction:** patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia)	**Category 1** Available in line with national guidance	Acute Specialist Services initiation then continued in Primary Care

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Patiromer sorbitex calcium 8.4g and 16.8g powder for oral suspension (Veltassa®) **SMC Number 2381** https://www.scottishmedicines.org.uk/media/6179/patiromer-veltassa-abbreviated-final-july-2021-for-website.pdf	**Indication under review:** treatment of hyperkalaemia in adults. **SMC restriction:** patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia)	**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	
RESPIRATORY			
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)	**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	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
Indacterol / mometasone furoate 125 micrograms / 62.5 micrograms and 125 micrograms / 127.5 micrograms and 125 micrograms / 260 micrograms (Atectura Breezhaler®) **SMC Number 2356** https://www.scottishmedicines.org.uk/media/5940/indacaterol-mometasone-atectura-breezhaler-abb-final-april-2021docx-for-website.pdf	**Indication under review:** as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta$_2$-agonists	**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	
Indacaterol / glycopyrronium / mometasone furoate 114 micrograms / 46 micrograms / 136 micrograms (Enerzair Breezhaler®) **SMC Number 2355** https://www.scottishmedicines.org.uk/media/5939/indacaterol-glycopyrronium-mometasone-furoate-enerzair-breezhaler-abb-final-april-2021docx-for-website.pdf	**Indication under review:** as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta$_2$-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.	**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	
Nintedanib 100mg and 150mg soft capsules (Ofev®) **SMC Number 2331** https://www.scottishmedicines.org.uk/media/6024/nintedanib-ofev-final-may-2021-for-website.pdf	**Indication under review:** in adults for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype other than idiopathic pulmonary fibrosis (IPF).	**Category 1** Available in line with national guidance	Acute Specialist Services

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
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	**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.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	
RHEUMATOLOGY			
Guselkumab 100mg solution for injection in pre-filled pen or syringe (Tremfya®) SMC Number 2360 https://www.scottishmedicines.org.uk/medicines-advice/guselkumab-tremfya-full-smc2360/	**Indication under review:** alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **SMC restriction:** (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and (iii) patients in whom TNF inhibitors are contraindicated or not tolerated.	**Category 2** Available in line with local guidance for prescribing	Acute Specialist Services
Filgotinib 100mg and 200mg film-coated tablets (Jyseleca®) SMC Number 2365 https://www.scottishmedicines.org.uk/medicines-advice/filgotinib-jyseleca-full-smc2365/	**Indication under review:** filgotinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). **SMC restriction:** in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF antagonist in whom rituximab is not appropriate.	**Category 2** Available in line with local guidance for prescribing	Acute Specialist Services
Upadacitinib 15mg prolonged-release tablets (Rinvoq®) SMC Number 2361 https://www.scottishmedicines.org.uk/media/5944/upadacitinib-rinvoq-abbreviated-final-april-2021docx-for-website.pdf	**Indication under review:** for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. Upadacitinib may be used as monotherapy or in combination with methotrexate. **SMC restriction:** for use in patients with psoriatic arthritis whose disease has not responded adequately to at least two conventional DMARDs, given either alone or in combination.	**Category 2 –** available in line with local guidance for prescribing	Acute Specialist Services

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
SUBSTANCE MISUSE			
Buprenorphine 74.2mg implant (Sixmo®) SMC Number 2372 https://www.scottishmedicines.org.uk/media/6541/buprenorphine-sixmo-final-september-2021-amended-201021-for-website.pdf	**Indication under review:** for substitution treatment for opioid dependence in clinically stable adult patients who require no more than 8 mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment.	**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	
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.			
Avelumab 20mg/mL concentrate for solution for infusion (Bavencio®) SMC Number 2359 https://www.scottishmedicines.org.uk/media/6187/avelumab-bavencio-final-july-2021-amended-050821-for-website.pdf	**Indication under review:** as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy.		
Atezolizumab (Tecentriq®) 1,200mg concentrate for solution for infusion SMC Number 2349 https://www.scottishmedicines.org.uk/media/6103/atezolizumab-tecentriq-final-june-2021-for-website.pdf	**Indication under review:** in combination with bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.		
Atezolizumab 840mg and 1,200mg concentrate for solution for infusion (Tecentriq®) SMC Number 2379 https://www.scottishmedicines.org.uk/media/6428/atezolizumab-tecentriq-final-october-2021-for-website.pdf	**Indication under review:** As monotherapy for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥50% tumour cells (TC) or ≥10% tumour-infiltrating immune cells (IC) and who do not have epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK)-positive NSCLC.		
Cabozantinib 20mg, 40mg and 60mg film-coated tablets (Cabometyx®) SMC Number 2386 https://www.scottishmedicines.org.uk/media/6332/cabozantinib-cabometyx-abbreviated-final-sept-2021-for-website.pdf	**Indication under review:** in combination with nivolumab for the first-line treatment of advanced renal cell carcinoma in adults.		
Mogamulizumab 4mg/mL concentrate for solution for infusion (Poteligeo®) SMC Number 2336 https://www.scottishmedicines.org.uk/media/6023/mogamulizumab-poteligeo-final-may-2021-amended-240521-for-website.pdf	**Indication under review:** treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy. **SMC restriction:** for the treatment of patients with advanced MF or SS (stage ≥IIB MF and all SS) following at least one prior systemic therapy, who are clinically ineligible for or refractory		
Niraparib 100mg hard capsules (Zejula®) SMC Number 2338 https://www.scottishmedicines.org.uk/media/5941/niraparib-zejula-final-april-2020-amended-4521docx-for-website.pdf	**Indication under review:** as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III or IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy		
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC Number 2362 https://www.scottishmedicines.org.uk/media/6177/nivolumab-opdivo-final-july-2021-for-website.pdf	**Indication under review:** as monotherapy for the treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy.		
Olaparib 100mg and 150mg film-coated tablets (Lynparza®) SMC Number 2366 https://www.scottishmedicines.org.uk/media/6338/olaparib-lynparza-final-september-2021-for-website.pdf	**Indication under review:** as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.		

Drug (approved by SMC)	SMC Advice
Olaparib 100mg and 150mg film-coated tablets (Lynparza®) SMC Number 2367 https://www.scottishmedicines.org.uk/media/6178/olaparib-lynparza-abbreviated-final-july-2021-for-website.pdf	**Indication under review:** as monotherapy maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.
Osimertinib 40mg and 80mg film-coated tablet (Tagrisso®) **SMC Number 2382** https://www.scottishmedicines.org.uk/media/6588/osimertinib-tagrisso-resub-final-december-2021docx-for-website.pdf	**Indication under review:** As monotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.
Osimertinib 40mg and 80mg film-coated tablets (Tagrisso®) SMC Number 2383 https://www.scottishmedicines.org.uk/media/6422/osimertinib-tagrisso-final-october-2021-for-website.pdf	**Indication under review:** as monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions (Ex19del) or exon 21 (L858R) substitution mutations. **SMC restriction:** treatment with osimertinib is subject to a three-year clinical stopping rule.
Pertuzumab and trastuzumab 600mg/600mg and 1,200mg/600mg solution for injection (Phesgo®) **SMC Number 2364** https://www.scottishmedicines.org.uk/media/6111/pertuzumab-plus-trastuzumab-phesgo-abbreviated-final-june-2021-amended-for-website.pdf	**Indication under review:** Early breast cancer (EBC) In combination with chemotherapy in: • the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence • the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence Metastatic breast cancer (MBC) In combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. **SMC restriction:** Restricted to use in line with previous SMC advice for pertuzumab and trastuzumab (see SMC2284; SMC2120; SMC2119; SMC No. 928/13; SMC No. 278/06).
Trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®) **SMC Number 2388** https://www.scottishmedicines.org.uk/media/6590/trastuzumab-deruxtecan-enhertu-final-december-2021docx-amended-241221docx-for-website.pdf	**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 unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens.
Trifluridine/tipiracil 15mg/6.14mg and 20mg/8.19mg film-coated tablets (Lonsurf®) **SMC Number 2329** https://www.scottishmedicines.org.uk/media/6026/trifluridinetipiracil-lonsurf-final-may-2021-for-website.pdf	**Indication under review:** As monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease. **SMC restriction**: for use as third line treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction In a phase III, randomised, double-blind study, trifluridine/tipiracil was associated with an improvement in overall survival compared with placebo.
Tucatinib 50mg and 150mg film-coated tablets **(Tukysa®)** **SMC Number 2398** https://www.scottishmedicines.org.uk/media/6591/tucatinib-tukysa-final-december-2021docx-for-website.pdf	**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.

Drug (approved by SMC)	SMC Advice
Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) **SMC Number 2380** https://www.scottishmedicines.org.uk/media/6423/pembrolizumab-keytruda-final-october-2021-for-website.pdf	**Indication under review:** as monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule
Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) SMC Number 2375 https://www.scottishmedicines.org.uk/media/6246/pembrolizumab-keytruda-final-august-2021-for-website.pdf	**Indication under review:** as monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule. In an open-label, phase III study, pembrolizumab monotherapy was associated with significantly improved progression-free survival compared with investigator's choice of chemotherapy in patients with metastatic MSI-H/dMMR colorectal cancer.
Selpercatinib, 40mg and 80mg hard capsules (Retsevmo®) SMC Number 2370 https://www.scottishmedicines.org.uk/media/6247/selpercatinib-retsevmo-final-august-2021-for-website.pdf	**Accepted for use** within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. **Indication under review:** Selpercatinib as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib. Selpercatinib as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib
Autologous anti-CD19-transduced CD3+ cells (KTE-X19) 0.4 to 2 × 108 cells dispersion for infusion (Tecartus®)* SMC Number 2351 accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. https://www.scottishmedicines.org.uk/media/6180/autologous-tecartus-final-july-2021-for-website.pdf	**Indication under review:** the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.
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)	
Anakinra 100mg solution for injection in a pre-filled syringe (Kineret®) **SMC Number 2449** https://www.scottishmedicines.org.uk/media/6540/anakinra-kineret-non-sub-final-november-2021-for-website.pdf	**Indication under review:** Treatment of Familial Mediterranean Fever (FMF). Kineret should be given in combination with colchicine, if appropriate.
Asfotase alfa 40mg/mL and 100mg/mL solution for injection(Strensiq®) **SMC Number 2433** https://www.scottishmedicines.org.uk/media/6427/asfotase-alfa-strensiq-non-sub-final-october-2021-for-website.pdf	**Indication under review:** Long-term enzyme replacement therapy in patients with paediatric-onset hypophosphatasia to treat the bone manifestations of the disease.
Avapritinib 100mg, 200mg and 300mg film-coated tablets (Ayvakyt®) **SMC Number 2424** https://www.scottishmedicines.org.uk/media/6329/avapritinib-ayvakyt-non-submission-final-sept-2021-for-website.pdf	**Indication under review:** As monotherapy for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) harbouring the platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation.
Delafloxacin 300mg powder for concentrate for solution for infusion and 450mg tablets (Quofenix®) **SMC Number 2393** https://www.scottishmedicines.org.uk/media/6105/delafloxacin-quofenix-non-sub-final-june-2021-for-website.pdf	**Indication under review:** treatment of community-acquired pneumonia in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents

Durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®) https://www.scottishmedicines.org.uk/media/6430/durvalumab-imfinzi-non-sub-final-october-2021-for-website.pdf	**Indication under review:** durvulumab in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer.
Elotuzumab 300mg and 400mg powder for concentrate for solution for infusion (Empliciti®) SMC Number 2407 https://www.scottishmedicines.org.uk/media/6182/elotuzumab-empliciti-non-sub-final-july-2021-for-website.pdf	**Indication under review:** In combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy.
Fostemsavir 600 mg prolonged-release tablets (Rukobia®) SMC Number 2389 https://www.scottishmedicines.org.uk/media/6106/fostemsavir-rukobia-non-sub-final-june-2021-for-website.pdf	**Indication under review:** In combination with other antiretrovirals for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen
Imipenem/cilastatin/relabactam 500mg/500mg/250mg powder for solution for infusion (Recarbrio®) SMC Number 2390 https://www.scottishmedicines.org.uk/media/6107/imipenem-cilastatin-relabactam-recarbrio-non-sub-final-june-2021-for-website.pdf	**Indication under review:** Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.
Isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa®) SMC Number 2423 https://www.scottishmedicines.org.uk/media/6335/isatuximab-sarclisa-non-submission-final-sept-2021-for-website.pdf	**Indication under review:** in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
Liraglutide 6mg/mL solution for injection in pre-filled pen (Saxenda®) SMC number 2378 https://www.scottishmedicines.org.uk/media/6360/liraglutide-saxenda-final-sept-2021-amended-081021-for-website.pdf	**Indication under review:** as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of: • ≥30kg/m² (obese), or • ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related co morbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.
Mercaptamine 25mg and 75mg (as bitartrate) gastro-resistant hard capsules (Procysbi®) SMC Number 2374 https://www.scottishmedicines.org.uk/media/6319/mercaptamine-procsybi-final-august-2021-amended-30821-for-website.pdf	**Indication under review:** For the treatment of proven nephropathic cystinosis. A phase III, open-label, crossover study demonstrated that extended-release mercaptamine (Procysbi®) was non-inferior to immediate-release mercaptamine in control of white blood cell cystine levels in patients with nephropathic cystinosis who were previously controlled on mercaptamine therapy.
Nitisinone 2mg, 5mg, 10mg and 20mg hard capsules and 4mg/mL oral suspension (Orfadin®) https://www.scottishmedicines.org.uk/media/6543/nitisinone-orfadin-non-sub-final-november-2021-for-website.pdf	**Indication under review:** Treatment of adult patients with alkaptonuria (AKU).
Olaparib 100mg and 150mg film-coated tablets (Lynparza®) SMC number 2436 https://www.scottishmedicines.org.uk/media/6433/olaparib-lynparza-non-sub-final-oct-2021-for-website.pdf	**Indication under review:** As monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments.

Olaparib 100mg and 150mg film-coated tablets (Lynparza®) **SMC number 2435** https://www.scottishmedicines.org.uk/media/6434/olaprib-lynparza-non-sub-final-october-2021-for-website.pdf	**Indication under review:** As monotherapy for the maintenance treatment of adult patients with germline BRCA1/2-mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen.
Ramucirumab 10 mg/mL concentrate for solution for infusion (Cyramza®) SMC Number 2291 https://www.scottishmedicines.org.uk/media/6025/ramucirumab-cyramza-non-sub-final-may-2021-for-website.pdf	**Indication under review: i**n combination with erlotinib for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor mutations.
Sebelipase alfa 2mg/mL concentrate solution (Kanuma®) SMC number 2437 https://www.scottishmedicines.org.uk/media/6425/sebelipase-alfa-kanuma-non-sub-final-october-2021-for-website.pdf	**Indication under review:** Long-term enzyme replacement therapy (ERT) in patients of all ages with lysosomal acid lipase (LAL) deficiency.
Tafamidis 61mg soft capsules (Vyndaqel®) SMC Number 2426 https://www.scottishmedicines.org.uk/media/6537/tafamidis-vyndaqel-resub-final-november-2021-for-website.pdf	**Indication under review:** for the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).
Vericiguat 2.5mg, 5mg and 10mg film-coated tablets (Verquvo®) SMC Number 2425 https://www.scottishmedicines.org.uk/media/6339/vericiguat-verquvo-non-submission-final-sept-2021-for-website.pdf	**Indication under review:** Treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilised after a recent decompensation event requiring IV therapy.

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/

Analgesia

Following a multi-disciplinary review the following formulary changes were agreed to the FV Formulary:

Opioid Section

- **Co-codamol 15/500 tablets** added to the Formulary. The tablets/caplets are the preferred preparation for co-codamol and paracetamol preparations.
- **Butec® patches** (buprenorphine 7 day patch) added to the Formulary. Should be prescribed as the brand Butec®.
- **Zomorph® capsules** (morphine sulphate) – preferred choice in new patients requiring a modified release morphine preparation. For patients with swallowing difficulties the contents of the capsule can be administered via semi-solid food such as yoghurt, puree, jam, or via an appropriate sized gastric or gatrostomy tube.
- **Morphgesic®** tablets are no longer a Formulary choice brand.

Brand name prescribing is recommended for all strong opioids to reduce the risk of confusion and error in dispensing and administration.

Neuropathic section

- **Nortriptyline** addition as a 2nd line choice in patients intolerant of amitriptyline.
- **Duloxetine 30mg and 60mg capsules** is the preferred 2nd line choice in new patients for neuropathic pain, in preference to gabapentinoids.
- **Qutenza patch** (capsaicin) are Specialist Use Only and should not be prescribed in Primary Care as application needs to be undertaken under the supervision of a physician.

Mental Health

Attention Deficit Hyperactivity Disorder (ADHD)

- The 1st, 2nd and 3rd line choices for the management of ADHD have been clarified.
- **Xaggitin® XL** is the preferred methylphenidate modified release preparation. Prescribe as the brand.

Melatonin in Neurodevelopmental Disorders

The use of crushed melatonin MR preparations in patients with swallowing difficulties is not supported due to the availability of other licensed formulations.

Wherever clinically appropriate prescribe the licensed melatonin formulations and strengths listed:

- 1st line melatonin 3mg tablets
- 2nd line melatonin 1mg, 2mg and 5mg modified release tablets, or melatonin 2mg, 3mg, 5mg immediate release capsules.
- 3rd line melatonin 1mg/1ml sugar free oral solution.

Licensed formulations of melatonin should be prescribed in new patients. Patients currently on an unlicensed alternative formulation, when next reviewed, should be considered for a switch to a licensed formulation as part of the review process and if clinically appropriate.

Disorders of Bone Metabolism

- Once weekly oral bisphosphonates should be prescribed in preference to daily bisphosphonates
- Bonisto® (alendronic acid) effervescent tablets is preferred to alendronic acid liquid in patients who are unable to swallow alendronic acid tablets as it is the more cost-effective formulation.
- Reminder for the need to prescribe calcium + vitamin D/ vitamin D supplements in patients prescribed bisphosphonates. A list of preferred FV formulations is included in the Formulary section.

Musculoskeletal

DMARDS

- Reminder that ciclosporin (Neoral®), methotrexate injection (Metoject®) and tacrolimus formulations should be prescribed by brand name due to differences in bioavailability and to avoid dispensing errors. Preferred brands are stated in brackets.

Gout

- Preferred 1st and 2nd line options for the management of acute and chronic gout have been specified.

Muscle relaxants

- **Tizanidine –** has been added to the Formulary as a 2nd line muscle relaxant. Specialist initiation/recommendation.

NSAIDS

- The Formulary choice oral NSAIDs have been updated – ibuprofen and naproxen are considered 1st line and celecoxib 2nd line. Diclofenac is no longer a Formulary choice oral NSAID.
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Quinine

- The formulary choice quinine formulation is quinine sulphate tablets. Quinine bisulphate is significantly more expensive and should no longer be prescribed in new patients. Patient currently prescribed quinine bisulphate should be reviewed and switched to an appropriate strength of quinine sulphate where clinically appropriate.
- Quinine is not recommended for routine treatment of leg cramps due to its potential toxicity. Quinine should only be used when non-pharmacological treatments have not worked (e.g. passive stretching exercises); the cramps are very painful or frequent and cause regular disruption to sleep. Other treatable causes of cramp should be excluded.
- Quinine sulphate 200-300mg at bedtime can be trialled for up to 8 weeks. If there is no benefit after 8 weeks then treatment should be stopped.
- In long-term use, patients should be monitored for adverse effects and it is recommended treatment should be interrupted at intervals of 3 months to assess the ongoing need for treatment.

Other Agreed Changes to the FV formulary

- **Clomifene** - Change in formulary status – Specialist initiation/recommendation. Can be continued in Primary Care.
- **Sylk®** vaginal lubricant - added to the Formulary - Specialist initiation/recommendation. Can be continued in Primary Care.
- **Pentosan polysulfate sodium (Elmiron®)** – Hospital specialist use only for the management of bladder pain syndrome as per SMC recommendation.
- **Aciclovir eye ointment** – has been added as a 2nd line option for viral eye infections where ganciclovir (Virgan®) eye ointment is unsuitable. Specialist initiation/recommendation.
- **Calcipotriol/betamethasone ointment** for the management of plaque psoriasis. Preferred brand is **Dalonev®** rather than Dovobet®. Dalonev® is more cost effective due to a primary care rebate scheme. Prescribe by brand name rather than generic to ensure Dalonev® is dispensed. Community pharmacies have been advised to adjust stock holdings due to this change.
- **Infliximab** - the preferred brand for use in new patients is now **Remsima®** as it is more cost-effective than the Inflectra® brand. Due to the availability of different biosimilars. Infliximab should always be prescribed by brand name only.

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