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ADTC Newsletter

New Drugs and Therapeutic Advances

Outlined in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix 1).
Please remember that the ADTC advises prescribers **not** to prescribe any drug that has not been recommended by Scottish Medicines Consortium (SMC) or has not yet been considered by SMC.

Where a medicine is not recommended for use by the Scottish Medicines Consortium (SMC) for use in NHS Scotland, including those medicines not recommended due to non-submission, this will be noted by the Area Drug and Therapeutics Committee New Drugs & Formulary Sub Group and the medicine will not be added to the NHS Forth Valley Formulary.

Where a medicine that has not been accepted by the SMC or NHS Health Improvement Scotland (HIS) following their appraisal on clinical and cost-effectiveness, there are Individual Patient Treatment Request (IPTR) and Peer Approved Clinical System (PACS) processes which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to pursue approval for prescribing, on a “case by case” basis for individual patients

A copy of these policies can be found at the Pharmacy page on the Quality Improvement Website on the following link: https://guidelines.staffnet.fv.scot.nhs.uk/pharmacy-and-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
HAEMATOLOGY			
Ravulizumab 300mg concentrate for solution for infusion (Ultomiris®) **SMC Number 2305** https://www.scottishmedicines.org.uk/media/5756/ravulizumab-ultomiris-final-jan-2021-for-website.pdf	**Accepted for restricted use within NHSScotland.** **Indication under review:** for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity • In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months. **SMC restriction:** under the advice of the national PNH service.	**Category 3 -** Available from a specialist centre in another NHS board	Prescribing would be from a specialist Centre
Fostamatinib 100mg and 150mg film-coated tablets (Tavlesse®) **SMC Number 2300** https://www.scottishmedicines.org.uk/media/5710/fostamatinib-tavlesse-final-dec-2020docx-for-website.pdf	**Accepted for restricted use within NHSScotland.** **Indication under review:** treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. **SMC restriction:** for the treatment of patients with severe symptomatic ITP or with a high risk of bleeding who have not had a suitable response to other therapies, including a thrombopoietin receptor-agonist (TPO-RA), or where use of a TPO-RA is not 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 Decision Pending
Avatrombopag 20mg film-coated tablets (Doptelet®) **SMC Number 2296** https://www.scottishmedicines.org.uk/media/5651/avatrombopag-doptelet-final-october-2020-for-website.pdf	**Accepted for use within NHSScotland.** **Indication under review:** treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.	**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 Decision Pending
HIV			
Doravirine/lamivudine/ tenofovir disoproxil fumarate 100mg/300mg/245mg film-coated tablets (Delstrigo®) **SMC Number 2333** https://www.scottishmedicines.org.uk/media/5816/doravirine-delstrigo-abbreviated-final-feb-2021-for-website.pdf	**Accepted for use within NHSScotland.** **Indication under review:** for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.	**Category 1 -** Available in line with national guidance	Acute Services
Doravirine 100mg film-coated tablets (Pifeltro®) **SMC Number 2332** https://www.scottishmedicines.org.uk/media/5811/doravirine-pifeltro-abbreviated-final-feb-2021-for-website.pdf	**Accepted for use within NHSScotland.** **Indication under review:** in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.	**Category 1 -** Available in line with national guidance	Acute Services

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
NEUROLOGY			
Ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia®) **SMC Number 2309** https://www.scottishmedicines.org.uk/media/5755/ozanimod-zeposia-final-jan-2021-amended-2221-for-website.pdf	**Accepted for restricted use within NHSScotland.** **Indication under review:** treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features. **SMC restriction:** suitable for or requesting an oral 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	Not Applicable as not included in Forth Valley Formulary
Onasemnogene abeparvovec 2 × 1013 vector genomes/mL solution for infusion (Zolgensma®) **SMC Number 2311** https://www.scottishmedicines.org.uk/media/5813/onasemnogene-abeparvovec-zolgensma-final-feb-2021-amended-010321docx-for-website.pdf	**Accepted for restricted use within NHSScotland.** **Indication under review:** treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene. **SMC restriction**: for the treatment of - patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or - pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene, where patients are expected to develop SMA type 1	**Category 3 -** Available from a specialist centre in another NHS board	Prescribing would be from a specialist Centre
RESPIRATORY			
Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 87mcg / 5mcg / 9mcg (Trimbow®) **SMC Number 2335** https://www.scottishmedicines.org.uk/media/5815/beclometasone-trimbow-md-abbreviated-final-feb-2021-for-website.pdf	**Accepted for use within NHSScotland.** **Indication under review:** maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.	**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 Decision Pending
Formoterol fumarate dihydrate / glycopyrronium bromide / budesonide 5mcg/9mcg/160mcg pressurised inhalation, suspension (Trixeo® Aerosphere) **SMC Number 2321** https://www.scottishmedicines.org.uk/media/5765/formoterol-fumarate-dihydrate-trixeo-aerosphere-abb-final-jan-2021-for-website.pdf	**Accepted for restricted use within NHSScotland.** **Indication under review:** maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. **SMC restriction:** in patients with severe COPD (forced expiratory volume in one second [FEV_1] less than 50% predicted normal).	**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	Not Applicable as not included in Forth Valley Formulary

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
RHEUMATOLOGY			
Secukinumab 150mg solution for injection in pre-filled syringe and 150mg solution for injection in pre-filled pen (Cosentyx®) **SMC Number 2308** https://www.scottishmedicines.org.uk/media/5712/secukinumab-cosentyx-final-december-2020docx-for-website.pdf	**Accepted for use within NHSScotland.** **Indication under review:** treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non steroidal anti inflammatory drugs.	**Category 1 -** Available in line with national guidance	Acute Services
Upadacitinib 15mg prolonged-release tablet (Rinvoq®) **SMC Number 2315** https://www.scottishmedicines.org.uk/media/5757/upadacitinib-rinvoq-final-jan-2021-for-website.pdf	**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 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 Services
SUBSTANCE MISUSE			
Buprenorphine/naloxone 2mg/0.5mg and 8mg/2mg sublingual film (Suboxone®) **SMC Number 2316** https://www.scottishmedicines.org.uk/media/5761/buprenorphine-naloxone-suboxone-abb-final-jan-2021-for-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. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction. **SMC restriction:** to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered 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	Not Applicable as not included in Forth Valley Formulary
ONCOLOGY			
Leuprorelin acetate 3.75mg (Prostap® SR DCS) and 11.25mg (Prostap® 3 DCS) powder and solvent for prolonged-release suspension for injection in pre-filled syringe **SMC Number 2320** https://www.scottishmedicines.org.uk/media/5751/leuprorelin-acetate-prostap-dcs-abc-abb-final-jan-2021-for-website.pdf	**Accepted for use** within NHSScotland **Indication under review:** as treatment in pre- and perimenopausal women with advanced breast cancer suitable for hormonal manipulation.	**Category 6** - Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Acute Services

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
ONCOLOGY			
Leuprorelin acetate 3.75mg (Prostap® SR DCS) and 11.25mg (Prostap® 3 DCS) powder and solvent for prolonged-release suspension for injection in pre-filled syringe **SMC Number 2319** https://www.scottishmedicines.org.uk/media/5752/leuprorelin-acetate-prostap-dcs-ebc-abb-final-jan-2021-for-website.pdf	**Accepted for use** within NHSScotland. **Indication under review:** as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence (young age, high grade tumour, lymph node involvement). In women who have received chemotherapy, premenopausal status must be confirmed after completion of chemotherapy	**Category 6** - Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Acute Services
Entrectinib 100mg and 200mg hard capsules (Rozlytrek®) **SMC Number 2295** https://www.scottishmedicines.org.uk/media/5812/entrectinib-rozlytrek-final-feb-2021docx-for-website.pdf	**Accepted for use within NHSScotland.** **Indication under review:** as monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, • who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and • who have not received a prior NTRK inhibitor • who have no satisfactory treatment options In a pooled analysis of three phase I/II studies in adults with metastatic or locally advanced NTRK fusion-positive solid tumours, 64% of patients achieved an objective response with entrectinib treatment. The median duration of response in these patients was 12.9 months. Positive objective response rate results were also reported in a phase I/Ib paediatric study.	**Category 1 -** available in line with national guidance	Acute Services
Trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) **SMC Number 2328** https://www.scottishmedicines.org.uk/media/5820/trametinib-mekinist-abbreviated-final-feb-2021-for-website.pdf	**Accepted for restricted use within NHSScotland.** **Indication under review:** in combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. **SMC restriction:** after first line treatment	**Category 1 -** available in line with national guidance	Acute Services
SMC NOT RECOMMENDED			
Afamelanotide 16mg implant (Scenesse®) **SMC Number 1251/17** https://www.scottishmedicines.org.uk/media/5758/afamelanotide-scenesse-final-jan-2021-for-website.pdf	**Indication under review:** prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).	**Category 4 –** not available as not recommend for use in NHS Scotland	Not Applicable as not recommended by SMC

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
SMC NOT RECOMMENDED			
Alpelisib 50mg, 100mg and 200mg film-coated tablets (Piqray®) **SMC Number 2339** https://www.scottishmedicines.org.uk/media/5759/alpelisib-piqray-non-sub-final-jan-2021-for-website.pdf	**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 therapy as monotherapy.	**Category 4 –** not available as not recommend for use in NHS Scotland	Not Applicable as not recommended by SMC
Apremilast 10mg, 20mg and 30mg film-coated tablets (Otezla®) **SMC Number 2340** https://www.scottishmedicines.org.uk/media/5760/apremilast-otezla-non-sub-final-jan-2021-for-website.pdf	**Indication under review:** Treatment of adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.	**Category 4 –** not available as not recommend for use in NHS Scotland	Not Applicable as not recommended by SMC
Imipenem/cilastatin/relabactam 500mg/500mg/250mg powder for solution for infusion (Recarbrio®) **SMC Number 2342** https://www.scottishmedicines.org.uk/media/5750/imipenem-cilastatin-relabactam-recarbrio-non-sub-final-jan-2021-for-website.pdf	**Indication under review:** Treatment of: • hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults. bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults	**Category 4 –** not available as not recommend for use in NHS Scotland	Not Applicable as not recommended by SMC
Mercaptamine 3.8 mg/mL eye drops solution (Cystadrops®) **SMC Number 2343** https://www.scottishmedicines.org.uk/media/5753/mercaptamine-cystadrops-non-sub-final-jan-2021-for-website.pdf	**Indication under review:** Treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis.	**Category 4 –** not available as not recommend for use in NHS Scotland	Not Applicable as not recommended by SMC
Omalizumab 75mg and 150 mg solution for injection in pre-filled syringe (Xolair®) **SMC Number 2344** https://www.scottishmedicines.org.uk/media/5754/omalizumab-xolair-non-sub-final-jan-2021-for-website.pdf	**Indication under review:** As add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control.	**Category 4 –** not available as not recommend for use in NHS Scotland	Not Applicable as not recommended by SMC

CHANGES ON ADTC DECISIONS FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
Budesonide 1mg orodispersible tablets (Jorveza®) SMC Number 2158 https://www.scottishmedicines.org.uk/media/5460/budesonide-jorveza-final-september-2020-for-website.pdf	**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.	**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	
Romosozumab 105mg solution for injection in pre-filled pen (Evenity®) SMC Number 2280 https://www.scottishmedicines.org.uk/media/5569/romosozumab-evenity-final-october-2020-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** treatment of severe osteoporosis in postmenopausal women at high risk of fracture. **SMC restriction:** to use in patients who have experienced a fragility fracture and are at imminent risk of another fragility fracture (within 24 months).	**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	

Formulary Changes/Additions/Amendments

The following changes to the Forth Valley Formulary have been agreed by the New Drugs & Formulary Group. following recent formulary section re-views.. Relevant *ScriptSwitch*® messages to support prescribers in primary care have been added to the clinical system.

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/

Key changes to the relevant Formulary sections are highlighted below.

Eye Conditions

Following a multi-disciplinary review involving stakeholders from Ophthalmology, Pharmacy and Community Optometrists the following Formulary changes were agreed:

- **Atropine 1% Minims are preferred** to the standard 10ml bottle. Atropine 1% Minims cost £15.10 for 20 unit doses compared with £131.89 for the 10ml bottle.
- **Formulations for dry eye** are now listed by disease severity and by Brand preference (preferred brands updated). They should be prescribed by Brand when a brand is specified.
- **Ganciclovir eye gel** is the formulation of choice for treatment of acute herpetic keratitis in preference to aciclovir.
- **Fusidic acid is no longer routinely recommended** for the treatment of bacterial eye infections and should be re-served for when chloramphenicol is ineffective or not tolerated. It is expensive at £35 per 5g tube.

Epilepsy and Movement Disorders

In conjunction with Forth Valley Neurology specialists the Formulary sections for Movement Disorders and Epilepsy were recently reviewed.

Key changes for epilepsy include:

- **Categorisation of all epilepsy medicines** in line with MHRA guidance.
- **Tegretol® Retard** as the carbamazapine brand of choice for patients with epilepsy.
- **Trileptal®** as the oxcarbazepine brand of choice for patients with epilepsy.
- **Generic prescribing of lamotrigine and leveti-racetam** unless brand prescribing is requested by specialist.

Key changes for movement disorders include:

- **Ipinnia® XL** as the ropinirole formulation of choice for movement disorders.
- **Pipexus® PR** as the pramipexole prolonged release (PR) formulation of choice for movement disorders.
- **Stanek®** as the formulation of choice where a combination Levodopa + Carbidopa + Entacapone product is required

Formulary choices for dietetic products

ONS, enteral feeds and paediatric/baby milk can now also be accessed via the link on the Formulary website.

Guidance Update

Vitamin B12 and Folate Guidance https://guidelines.staffnet.fv.scot.nhs.uk/?s=vitamin+b12	This has been added to the QI website The Forth Valley B12 and Folate Guidance was recently updated. Points of interest: • Addition of guidance on management of B12 in patients prescribed metformin and on borderline results. • No evidence of benefit from injections more frequently than 3 monthly once stabilised, unless neurological condition. • **Intramuscular** (IM) hydroxocobalamin **remains the route of choice** when B12 replacement is indicated. • High-dose oral B12 is reserved for patients unable to tolerate IM B12 and **only on recommendation from Haematology**. Cyanocobalamin 1mg tablets are now licensed as the brand Orobalin® and included in the Formulary for specialist initiation. • A useful flowchart is included to aid decision making.

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