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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
CARDIOLOGY			
Dapagliflozin 10mg film-coated tablets (Forxiga®) **SMC Number 2322** https://www.scottishmedicines.org.uk/media/5877/dapagliflozin-forxiga-final-march-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 2** – Available in line with local guidance for prescribing. To be used as an add on to maximally tolerated other therapies for heart failure Will be recommended by the heart failure specialist who will check the baseline renal function and prescribing can then be initiated/continued in primary care.	Acute & Specialist Services and Primary Care
NEUROLOGY			
Galcanezumab 120mg solution for injection in pre-filled pen (Engality®) **SMC Number 2313** https://www.scottishmedicines.org.uk/media/5872/galcanezumab-emgality-final-march-2021-amended-060421-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** prophylaxis of migraine in adults who have at least 4 migraine days per month. **SMC restriction:** for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.	**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 medicine. Preferred formulary choice is erenumab	Not applicable
RENAL			
Ravulizumab 300mg/3ml and 1,100mg/11ml concentrate for solution for infusion (Ultomiris®) **SMC Number 2330** https://www.scottishmedicines.org.uk/media/5942/ravulizumab-ultomiris-ahus-final-april-2021docx-for-website.pdf	**Accepted for restricted use** within NHSScotland. **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 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.	Not applicable

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
RESPIRATORY			
Dupilumab 200mg and 300mg solution for injection in pre-filled syringe and pen (Dupixent®) SMC Number 2317 https://www.scottishmedicines.org.uk/media/5871/dupilumab-dupixent-final-march-2021-amended-190321-for-website.pdf	**Accepted for restricted use** within NHSScotland. **Indication under review:** in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. **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.	Not applicable
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	**Accepted for use** within NHSScotland. **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 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.	Not applicable
RHEUMATOLOGY			
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	**Accepted for restricted use** within NHSScotland. **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 (cDMARDs), given either alone or in combination.	**Category 6 –** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
ULTRA-ORPHAN			
Ataluren 125mg, 250mg, and 1,000mg granules for oral suspension (Translarna®) **SMC Number 2327** https://www.scottishmedicines.org.uk/media/5874/umar-ataluren-translarna-final-march-2021-for-website.pdf	**Indication under review:** Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older. The presence of a nonsense mutation in the dystrophin gene should be determined by genetic testing.	Not currently listed in the Ultra-orphan pathway. Follow non-formulary process if necessary.	
ONCOLOGY			
Acalabrutinib 100mg hard capsules (Calquence®) **SMC Number 2348** https://www.scottishmedicines.org.uk/media/5876/acalabrutinib-calquence-2348-abbreviated-final-march-2021-for-website.pdf	**Accepted for restricted use within NHSScotland** **Indication under review:** As monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. **SMC restriction:** For adults with relapsed/refractory CLL who have had at least one previous therapy, in whom chemo-immunotherapy is unsuitable**.**	**Catergory 6 -** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable
Acalabrutinib 100mg hard capsules (Calquence®) **SMC Number 2346** https://www.scottishmedicines.org.uk/media/5875/acalabrutinib-calquence-2346-abbreviated-final-march-2021-for-website.pdf	**Accepted for restricted use within NHSScotland** **Indication under review**: as monotherapy or in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). **SMC restriction:** as monotherapy for the treatment of adult patients with previously untreated CLL who have a 17p deletion or TP53 mutation and in whom chemo-immunotherapy is unsuitable.	**Catergory 6 -** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable
Isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa®) **SMC Number 2303** https://www.scottishmedicines.org.uk/media/5873/isatuximab-sarclisa-final-march-2021-amended-060421-for-website.pdf	**Accepted for restricted use within NHSScotland** **Indication under review**: in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy. **SMC restriction**: patients receiving fourth-line therapy.	**Catergory 6 -** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable
Encorafenib 50mg and 75mg hard capsules (Braftovi®) **SMC Number 2312** https://www.scottishmedicines.org.uk/media/5937/encorafenib-braftovi-final-april-2021docx-for-website.pdf	**Accepted for use within NHSScotland** **Indication under review:** In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, who have received prior systemic therapy.	**Catergory 6 -** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
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	**Accepted for use within NHSScotland** **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.	**Catergory 6 -** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable
Chlormethine hydrochloride 160 micrograms/g gel (Ledaga®) **SMC Number 2318** https://www.scottishmedicines.org.uk/media/5936/chlormethine-hydrochloride-ledaga-final-april-2021docx-for-website.pdf	**Accepted for use within NHSScotland** **Indication under review:** for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients.	**Catergory 6 -** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Not applicable
SMC NOT RECOMMENDED			
Glycopyrronium / formoterol fumarate dihydrate 7.2 micrograms / 5 micrograms pressurised inhalation, suspension (Bevespi Aerosphere®) **SMC Number 2377** https://www.scottishmedicines.org.uk/media/5938/glycopyrronium-bevespi-aerosphere-non-sub-final-april-2021docx-for-website.pdf	**Indication under review:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	**Category 4** – Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)	Not Applicable

CHANGES ON ADTC DECISIONS FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
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	**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 medicine.	Not applicable

CHANGES ON ADTC DECISIONS FOR SMC APPROVED DRUGS				
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**	**Area of Prescribing**
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	**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 medicine.	Not applicable
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	**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 medicine.	Not applicable
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	**Category 1** Available in line with national guidance (link to SMC advice)	Acute & Specialist Services
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	**Category 1** Available in line with national guidance (link to SMC advice)	Acute & Specialist Services

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 reviews. 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/

Nausea and Labyrinth Disorders

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

- **Metoclopramide** is the first line choice if a *Dopamine Receptor Antagonist* is indicated; domperiodone remains available as a second line option.
- **Ondansetron standard tablets** are the first line choice if a *Serotonin (5HT3) Receptor Antagonists* is indicated. For patients with swallowing difficulties the preferred formulation are the **orodispersible films** as they are more cost- effective than orodispersible tablets.
- **Cyclizine, cinnarizine, prochlorperazine (standard tablets)** remain as Formulary choices when indicated.

Mental Health

In conjunction with Forth Valley Division of Psychiatry and Mental Health Pharmacy the Formulary sections for Mental Health Disorders were recently reviewed.

Key changes for Dementia:

- **Alzest**® as the rivastigmine patch brand of choice.

Key changes for Depression:

- Prescribe fluoxetine **in multiples of 20 mg capsules.**

Other formulations of fluoxetine are expensive.

Key changes for Bipolar disorder:

Syonell® as the valproate semisodium brand of choice. Depakote® no longer preferred.

Valproate Formulary restrictions

- Sodium valproate/valproate salts remain formulary for the treatment of epilepsy, mania and bipolar disorder in males.
- Sodium valproate/valproate salts shall only be prescribed for female adults who have the ability to bear children and for children for the treatment of epilepsy.
- Any new initiation for indications other than epilepsy for females who have the ability to bear children (including migraine, mania and bipolar disorder) will be non formulary across NHS Forth Valley and **subject to the IPTR process**.
- All prescribing of valproate in patients of child bearing potential should follow the **MHRA PREVENT** guidance.
- Following a MHRA request pack sizes of valproate containing medicines have **reduced from 100 tablets to 30 tablets** to facilitate dispensing of original packs — **quantities on prescription should be reviewed and aligned to multiples of 30 to ensure only original full packs are dispensed**.

New Formulary indications for SLGT2 inhibitors (gliflozins)

- **Dapagliflozin -** approved as an add-on for the treatment of symptomatic chronic heart failure with reduced ejection fracture in patients who are on optimised therapy but remain symptomatic. Initiation and continuation in Primary Care on the recommendation of a Heart Failure specialist.
- **Canagliflozin -** approved for restricted use to improve renal outcome in patients with Type 2 Diabetes with evidence of diabetic kidney disease (ACR 30 mg/mmol) for those who have suboptimal glycaemic control, BMI ≥30, and an HbA1c of 75mmol/mol. Can be initiated in Primary Care

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