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NHS Forth Valley

ADTC Newsletter
New Drugs & Therapeutic Advances

Outlined below in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix I).
Please remember that the ADTC advises prescribers **not** to prescribe any drug that has been not 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 Drug 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 is a 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 Intranet on the following link:
http://intranet.fv.scot.nhs.uk/web/FILES/Pharmacyfiles/NHSFVIPTRpolicywithappendicesv1_3final.pdf
http://staffnet.fv.scot.nhs.uk/a-z/pharmacy/

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 Recommended 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 Therapeutics Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in future.
For full SMC advice on specific drugs please refer to the SMC website **www.scottishmedicines.org**

Categories

Drugs Accepted for Use / 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

The ADTC recommends that prescribers may prescribe these drugs in accordance with SMC advice, unless they are not recommended by SMC

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Cardiology		
Evolocumab 140mg solution for injection in pre-filled syringe / 140mg solution for injection in pre-filled pen / 420mg solution of injection in cartridge (Repatha®) **SMC No 2133** https://www.scottishmedicines.org.uk/media/3852/evolocumab-repatha-non-sub-oct-2018.pdf	**Not recommended** **Indication under review:** In adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: • in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or, • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.	**Category 4**
Neurology		
Brivaracetam, 10mg, 25mg, 50mg, 75mg, 100mg film-coated tablets; 10mg/Ml oral solution; 10mg/Ml solution for injection/infusion (Briviact®) **SMC No 2113** https://www.scottishmedicines.org.uk/media/3956/brivaracetam-briviact-abb-final-nov-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from 4 years to ≤15 years of age with epilepsy. **SMC restriction:** for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	**Category 1**
Ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®) **SMC No 2121** https://www.scottishmedicines.org.uk/media/3966/ocrelizumab-ocrevus-rrms-resub-final-nov-2018-amended-051218-for-website.pdf	**Accepted for restricted use** **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:** Treatment of relapsing remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features who are contra-indicated or otherwise unsuitable for	**Category 6**
Fampridine 10mg prolonged-release tablet (Fampyra®) **SMC No 2107** https://www.scottishmedicines.org.uk/media/3853/fampridin	**Not recommended** **Indication under review:** For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).	**Category 4**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
e-fampyra-resubmission-final-oct-2018.pdf		
Oncology		
Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) **SMC No 2103** https://www.scottishmedicines.org.uk/media/3850/atezolizumab-tecentriq-final-oct-2018.pdf	**Not recommended** **Indication under review:** As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy.	**Category 4**
Dinutuximab beta 4.5mg/ml concentrate for solution for infusion (Qarziba®) **SMC No 2105** https://www.scottishmedicines.org.uk/media/3851/dinutuximab-beta-quarziba-final-oct-2018.pdf	**Accepted for use** **Indication under review:** for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.	**Category 1**
Fosaprepitant 150mg powder for solution for infusion (Ivemend) **SMC No 2108** https://www.scottishmedicines.org.uk/media/3854/fosaprepitant-ivemend-abb-final-oct-2018.pdf	**Accepted for use** **Indication under review:** prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in paediatric patients aged 6 months to 17 years. Fosaprepitant is given as part of a combination therapy.	**Category 1**
Nivolumab 10mg/Ml concentrate for solution for infusion (Opdivo®) **SMC No 2112** https://www.scottishmedicines.org.uk/media/3958/nivolumab-opdivo-final-nov-2018-for-website.pdf	**Accepted for use** **Indication under review:** As monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.	**Category 1**
Pembrolizumab 25mg/Ml concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) **SMC No 2143** https://www.scottishmedicines.org.uk/media/3959/pembrolizumab-keytruda-non-sub-final-nov-2018-for-website.pdf	**Not recommended** **Indication under review:** As monotherapy for the treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a ≥50% TPS and progressing on or after platinum-containing chemotherapy.	**Category 4**
Pertuzumab 420mg concentrate for solution for infusion (Perjecta®) **SMC No 2119** https://www.scottishmedicines.org.uk/media/3960/pertuzumab-perjeta-resub-final-nov-2018-for-website.pdf	**Accepted for use** **Indication under review:** for use in combination with trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.	**Category 1**
Opthalmology		

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ciclosporin 1mg/Ml (0.1%) eye drop emulsion (Verkazia®) **SMC No 2111** https://www.scottishmedicines.org.uk/media/3957/ciclosporin-verkazia-final-nov-2018-for-website.pdf	**Accepted for use** **Indication under review:** treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.	**Category 1**

Formulary Changes

Current Product	Changed to	Comments
Thick and Easy®	Thick and Easy Clear®	Replaces previous formulation.
Lacri-lube®	White Soft Paraffin (Xailin Night®)	Lacri-Lube – currently supply issues, is more cost effective.
True You test strips	4 Sure Smart	True You Test Strips being discontinued. Manufacturer has replaced with 4 Sure Smart test stips.

Changes on ADTC decisions for SMC Accepted for Use Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Dermatology			
Dimethyl fumarate 30mg and 120mg gastro-resistant tablets (Skilarence®) SMC No 1313/18 https://www.scottishmedicines.org.uk/media/3277/dimethyl-fumarate-skilarence-final-march-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy. **SMC restriction:** for use in patients in whom non-biologic systemic treatments (methotrexate, ciclosporin and acitretin) are not appropriate or have failed and who are considered unsuitable for biologic therapy therapy given their current disease state or personal preference.	**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
Rheumatology			
Ixekizumab (Talz®) 80mg solution for injection in pre-filled syringe or pen https://www.scottishmedicines.org.uk/media/3763/ixekizumab-taltz-final-sept-2018-amended-230918-for-website.pdf	**Accepted for restricted use** **Indication under review:** Ixekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. **SMC restriction:** patients whose disease has not responded adequately to at least two conventional DMARDs given either alone or in combination, and who have had an inadequate response to a tumour necrosis factor (TNF)-inhibitor.	**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
Drug (approved by SMC)	**SMC Advice**	**Previous decision**	**Updated FV Formulary position**

Sexual Health			
Levonorgestrel (Levosert®) 20 microgram/24 hours intrauterine delivery system **SMC No 1058/15** https://www.scottishmedicines.org.uk/media/1932/levonorgestrel__levosert__abb_final_may_2015_for_website.pdf	**Accepted for use** **Indication under review:** Contraception. Heavy Menstrual 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	**Category 1** Available in line with national guidance
Levonorgestrel 19.5mg intrauterine delivery system (Kyleena®) **SMC No 1299/18** https://www.scottishmedicines.org.uk/media/3109/levonorgestrel_kyleena_final_jan_2018_for_website.pdf	**Accepted for use** **Indication under review:** Contraception up to 5 years.	**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

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