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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 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 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 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 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 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

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
Endocrinology		
Dapagliflozin 5mg film coated tablets (Forxiga®) **SMC No 2185**	**Accepted for use** **Indication under review:** In adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥27kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.	**Category 5 –** Not routinely available as clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicine
HIV		
Dolutegravir 50mg / lamivudine 300mg film-coated tablets (Dovato®) **SMC No 2205**	**Accepted for use** **Indication under review:** for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.	**Category** 1 – available in line with national guidance Acute use only
Oncology		
Dacomitinib 15mg, 30mg and 45mg film-coated tablets (Vizimpro®) **SMC No 2184**	**Accepted for use** **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 epidermal growth factor receptor (EGFR)-activating mutations.	**Category** 1 – available in line with national guidance Acute use only
Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) **SMC No 2187**	**Accepted for restricted use** **Indication under review:** In combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in adults. **SMC restriction:** in combination with carboplatin and paclitaxel in patients whose tumours do not express programmed death ligand 1 (PD-L1) with a ≥50% tumour proportion score (TPS). Treatment with pembrolizumab is subject to a two-year clinical stopping rule.	**Category** 1 – available in line with national guidance Acute use only
Tisagenlecleucel 1.2 x 106 to 6 x 108 cells dispersion for infusion	**Accepted for use** **Indication under review:** for adult patients with relapsed or refractory	**Category** 1 – available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
(Kymriah®) **SMC No 2200**	diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.	Acute use only
Women & Children		
Ospemifene 60mg film-coated tablets (Senshio®) **SMC No 2170**	**Accepted for use** **Indication under review:** Treatment of moderate to severe symptomatic vulvar and vaginal atrophy (VVA) in post-menopausal women who are not candidates for local vaginal oestrogen therapy.	**Category 6** – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Not Recommended		
Eribulin 0.44mg/mL solution for injection (Halaven®) **SMC No 2231**	**Indication under review:** Treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.	**Category 4 –** not available as not recommended for use
Melatonin 1mg and 5mg prolonged-release tablets (Slenyto®) **SMC No 2168**	**Indication under review:** Treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.	**Category 4 –** not available as not recommended for use
Osimertinib 40mg and 80mg film-coated tablet (Tagrisso®) **SMC No 2171**	**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.	**Category 4 –** not available as not recommended for use

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Buprenorphine 8/16/24/32/64/96/128mg prolonged-release solution for injection (Buvidal®)	**Accepted for restricted use** **Indication under review:** treatment of opioid dependence within a framework of medical. Social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over. **SMC restriction**: use in patients in whom methadone is not suitable and for whom the use of buprenorphine is considered 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 medicines.
E**mpagliflozin plus linagliptin 10mg/5ml, 25mg/5ml film coated tablets (Glyxambi®) SMC No 1236/17**	**Accepted for restricted use** **Indication under review:** in adults aged 18 years and older with type-2 diabetes mellitus: • To improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Glyxambi® do not provide adequate glycaemic control • When already being treated with the free combination of empagliflozin and linagliptin **SMC restriction**: restricted to use in line with the previous SMC advice on empagliflozin and linagliptin.	**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.
Perampanel 0.5mg/mL oral suspension (Fycompa®) SMC No 2172	**Accepted for restricted use** **Indication under review:** for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in adult and adolescent patients from 12 years of age with epilepsy. **SMC restriction**: use as a second-line adjunctive treatment in patients with refractory partial onset epilepsy who are unable to swallow perampanel tablets. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy.	**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.

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