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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 rejected 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) process 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 this policy 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

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://www.qifv.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.

SMC Independent Review Panel

Where there are no significant new data or analyses, the sponsor company may ask that SMC convenes an Independent Review Panel (IRP) to look again at the existing data and analyses. An IRP may only be requested after a first SMC assessment has been completed, but can then be requested at any time when the drug is not in an SMC assessment process.
The IRP will be appointed by the SMC on the advice from the Chairman and Secretariat, and shall comprise 7 members:

- 3 members (where possible) appointed from the SMC/NDC (people who, by reason of absence, have not previously been involved in the particular submission, including former members of SMC or NDC), one of whom shall be appointed to chair the panel.

- 4 members (or more if required) appointed from Scottish Area Drug and Therapeutics Committees (or their successors/equivalents) and/or other respected experts in the relevant scientific field, who need not necessarily be working in Scotland.

The IRP will review the original submission(s) considered by the pharmacy and health economic assessment teams, the output from these review teams and the views of the NDC and SMC. Should support and advice be required then this shall be provided by the usual Assessment Teams, but will be provided by persons not involved in the original review(s)/ assessment(s).
The timeline from notification to request an IRP and publication of the final SMC advice is expected to be at least 6 months, due to the requirement to convene the panel and chair.
The IRP will report back to the SMC who shall remain the final arbiter in all cases.

NICE guidance

NICE Single technology Appraisal (STA): SMC is the source of advice for Scotland on new drug therapies and the NICE STA process therefore has **no status in Scotland**. If a NICE STA endorses a drug that was not recommended by the SMC, it is open to the manufacturers to resubmit the drug to SMC with new evidence.

NICE Multiple Technology Appraisal (MTA): NHS Healthcare Improvement Scotland (NHS HIS) reviews MTAs and decides whether the recommendations should apply in Scotland where Healthcare Improvement Scotland (HIS) decides that an MTA should apply in Scotland, the NICE guidance supersedes SMC advice. Unlike the SMC process, MTAs examine a disease area or a class of drugs and usually contain new evidence gathered after the launch of drugs or new economic modelling.

This information is reviewed by the New Drugs group on a routine basis.

HIS Comments on NICE Single Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE technology appraisal guidance – 358 Tolvaptan for treating autosomal dominant polycystic kidney disease	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/358**	**Forthcoming Submission** **Indication**: to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease in adults with CKD stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.	**Not applicable**	No
NICE technology appraisal guidance - 359 Idelalisib for treating chronic lymphocytic leukaemia	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/359**	**Accepted for restricted use** **Indication under review**: in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • Who have received at least one prior therapy, or • As first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy **SMC restriction**: patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	9/3/15	Yes
NICE technology appraisal guidance - 360 Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/360**	**Accepted for use** **Indication under review**: in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	9/2/15	Yes

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No

No Multiple Technology appraisals were reviewed

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**

Drugs Approved / Not Recommended By SMC

Category 1	Included on the NHS Board formulary for the indication in question
Category 2	Included pending protocol
Category 3	Not included on the NHS Board Formulary because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary
Category 4	Not included on the NHS Board Formulary because clinicians do not support the formulary inclusion
Category 5	Not included on the NHS Board Formulary because clinicians have not responded to an invitation to apply for formulary inclusion to this medicine
Category 6	Not included pending protocol

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
Anakinra (Kineret®) 100mg solution for injection in a pre-filled syringe SMC No 1116/15	**Not recommended** **Indication under review:** Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above, including: • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Muckle-Wells Syndrome (MWS) • Familial Cold Autoinflammatory Syndrome (FCAS)	**Not recommended by SMC therefore not included in the formulary**
Atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®) SMC No 1098/15 **Product Update**	**Accepted for use** **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir.	**Category 2**
Atomoxetine oral solution 4mg/mL (Strattera®) SMC No 1107/15 **Product Update**	**Accepted for restricted use** **Indication under review**: treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD. **SMC restriction**: to use in patients who are unable to swallow capsules.	**Category 1**
Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) SMC No 806/12 **Re-submission**	**Accepted for restricted use** **Indication under review:** In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. **SMC restriction:** In patients with FIGO stage IV disease	**Category 6**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ceritinib 150mg hard capsules (Zykadia®) SMC No 1097/15	**Accepted for use** **Indication under review:** Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.	**Category 6**
Co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®) SMC No 316/06 **Re-submission**	**Not recommended** **Indication under review:** treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.	**Not recommended by SMC therefore not included in the formulary**
Denosumab (Xgeva)®) 120mg solution for injection SMC No 1119/15	**Not recommended** **Indication under review:** Adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity	**Not recommended by SMC therefore not included in the formulary**
Edoxaban tosilate 15mg, 30mg, 60mg film-coated tablets (Lixiana®) SMC No 1090/15	**Accepted for use** **Indication under review:** Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	**Category 4**
Edoxaban tosilate15mg, 30mg and 60mg film-coated tablets (Lixiana®) SMC No 1095/15	**Accepted for use** **Indication under review:** for prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).	**Category 4**
Efavirenz 50mg, 100mg and 200mg hard capsules and 600mg film-coated tablets (Sustiva®) **Product Update**	**Accepted for use** **Indication under review:** antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3.5kg.	**Category 1**
Everolimus (Certican®) 0.25mg, 0.5mg and 0.75mg tablets SMC No 1117/15	**Not recommended** **Indication under review:** • Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a cardiac transplant • Prophylaxis of organ rejection in patients receiving a hepatic transplant	**Not recommended by SMC therefore not included in the formulary**
Gefitinib 250mg film-coated tablets (Iressa®) SMC No 615/10 **2nd Re-submission**	**Accepted for restricted use** **Indication under review:** the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK). **SMC restriction**: in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy.	**Category 6**
Glatiramer acetate 40mg/mL solution for injection prefilled syringes (Copaxone®) SMC No 1108/15 **Product Update**	**Accepted for use** **Indication under review:** treatment of relapsing forms of multiple sclerosis (MS).	**Category 6**
Ivermectin, 10mg/g, cream (Soolantra®) SMC No 1104/15	**Accepted for restricted use** **Indication under review:** topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.	**Category 6**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Lenalidomide, 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®) SMC No 1096/15	**Accepted for restricted use** **Indication under review:** treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. **SMC restriction**: for use in patients unsuitable for thalidomide-containing regimens	**Category 2**
Naloxegol 12.mg and 25mg film-coated tablets (Moventig®) SMC No 1106/15	**Accepted for use** **Indication under review:** the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s).	**Category 6**
Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1086/15	**Accepted for use** **Indication under review:** as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.	**Category 6**
Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1087/15	**Not recommended** **Indication under review:** as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously treated with ipilimumab.	**Not recommended by SMC therefore not included in the formulary**
Raltegravir granules for oral suspension 100mg (Isentress®) SMC No 1102/15 **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks. **SMC restriction:** patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir granules should be prescribed under the supervision of specialists in paediatric HIV.	**Category 1**
Raltegravir chewable tablets 25mg, 100mg (Isentress®) SMC No 1113/15 **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in children from the age of 4 weeks to <2 years. **SMC restriction:** patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir chewable tablets should be prescribed under the supervision of specialists in paediatric HIV.	**Category 1**
Regorafenib (Stivarga®) 40mg film-coated tablets Smc No 1118/15	**Not recommended** **Indication under review:** Adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies	**Not recommended by SMC therefore not included in the formulary**
Tiotropium/olodaterol 2.5 microgram/ 2.5 microgram inhalation solution (Spiolto® Respimat®) SMC No 1099/15 **Product Update**	**Indication under review:** maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	**Category 4**
Triamcinolone hexacetonide 20mg/mL suspension for injection SMC No 1103/15 **Product Update**	**Accepted for use** **Indication under review:** juvenile idiopathic arthritis (JIA).	**Category 1**

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Ceftobiprole 500mg powder for concentrate (Zevtra®)	**Accepted for restricted use** **Indication under review:** Ceftobiprole is indicated for the treatment of the following infections in adults: • Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) • Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents. **SMC restriction:** for use in the treatment of HAP (excluding VAP) when activity is required against suspected methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative pathogens (including *Pseudomona aeruginosa*, *Escherichia coli* and *Klebsiella pneumoniae*) and when combination treatment that includes vancomycin or teicoplanin is inappropriate or has not been tolerated, or when treatment modification is required, i.e. as an alternative to linezolid-based regimens.	Category 6 30/7/15	Category 4
Ciclosporin 1mg/mL (0.1%) eye drop emulsion (Ikervis®)	**Accepted for use** **Indication under review:** treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.	Category 6 30/9/15	Category 1

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