May2017
Vol. 14 No. 3

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
No submissions				

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE MTA Guidance No 439 – Cetuximab and panitumumab for previously untreated metastatic colorectal cancer	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/439	**Cetuximab –** accepted for restricted use for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten rat sarcoma (KRAS) wild-type metastatic colorectal cancer in combination with chemotherapy **Panitumumab** – not recommended	**15/1/10** **5/6/15**	**Yes** **No**

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 – date decision expected to be included

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
Alectinib hydrochloride (Alecensa®) 150mg hard capsules SMC No 1257/17 https://www.scottishmedicines.org.uk/files/advice/alectinib_hydrochloride_Alecensa_Non_Sub_FINAL_April_2017_for_website.pdf	**Not recommended** **Indication under review:** As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib.	**Category 4** Not available as not recommended for use in Scotland
Belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) SMC No 775/12 https://www.scottishmedicines.org.uk/files/advice/belimumab_Benlysta_Resub_FINAL_April_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. **SMC restriction:** patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®) SMC No 1216/17 https://www.scottishmedicines.org.uk/files/advice/ibrutinib_Imbruvica_Resub_FINAL_March_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** In adult patients for the treatment of relapsing forms of multiple sclerosis. **SMC restriction:** for use • in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or • in patients with RRMS with an inadequate response to disease modifying 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
Emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No 1225/17 https://www.scottishmedicines.org.uk/files/advice/emtricitabine_tenofovir_disoproxil_Truvada_FINAL_March_2017_for_website.pdf	**Accepted for use** **Indication under review:** In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Idebenone (Raxone®) 150mg film-coated tablets SMC No 1226/17 https://www.scottishmedicines.org.uk/files/advice/idebenone_Raxone_FINAL_April_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). **SMC restriction:** to patients with LHON who are not yet blind i.e. they do not meet the UK criteria to be registered as severely sight impaired.	**Category 1** Available in line with national guidance
Ibrutinib 140mg hard capsules (Imbruvica®) SMC No 1151/16 https://www.scottishmedicines.org.uk/files/advice/ibrutinib_Imbruvica_Resub_FINAL_March_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. **SMC restriction:** patients with relapsed/refractory CLL and for whom fludarabine-based regimens are inappropriate	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Insulin aspart (Fiasp®) 100 units/mL solution for injection in vial; solution for injection in cartridge (Penfill®); solution for injection in pre-filled pen (FlexTouch®) SMC No 1227/17 **Product Update** https://www.scottishmedicines.org.uk/files/advice/insulin_aspart_Fiasp_Abbreviated_FINAL_March_2017_for_website.pdf	**Accepted for use** **Indication under review:** treatment of diabetes mellitus in adults.	**Category 2** Available in line with local guidance for prescribing
Ixekizumab 80mg solution for injection (Taltz®) SMC No 1223/17 **Amended advice** https://www.scottishmedicines.org.uk/files/advice/ixekizumab_Taltz_FINAL_March_2017_Amended_05.04.17_for_website.pdf	**Accepted for restricted use** **Indication under review:** moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** patients who have failed to respond to standard systemic therapies, are intolerant to, or have a contra-indication to these treatments and including patients who have failed on one or more tumour necrosis factor (TNF) antagonists.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Liraglutide (Saxenda®) 6mg/mL solution for injection in pre-filled syringe SMC no 1247/17 https://www.scottishmedicines.org.uk/files/advice/liraglutide_Saxenda_Non_Sub_FINAL_April_2017_for_website.pdf	**Not recommended** **Indication under review:** as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of • ≥ 30kg/m² (obese), or • ≥ 27kg/m² to < 30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.	**Category 4** Not available as not recommended for use in Scotland
Micronised progesterone vaginal capsules 200mg (Utrogestan®) SMC No 935/13 https://www.scottishmedicines.org.uk/files/advice/micronised_progesterone_Utrogestan_Vaginal_FINAL_April_2017_Amended_12.04.17_for_website.pdf	**Accepted for use** **Indication under review:** in women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.	**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
Nepafenac 3mg/mL eye drops, suspension (Nevanac®) SMC No 1228/17 https://www.scottishmedicines.org.uk/files/advice/nepafenac_Nevenac_Abbreviated_FINAL_March_2017_for_website.pdf	**Accepted for use** **Indication under review:** reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ofatumumab (Arzerra®) 100mg & 1000mg concentrate for solution for infusion SMC No 1237/17 https://www.scottishmedicines.org.uk/files/advice/ofatumumab_Arzerra_Non_Sub_FINAL_March_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of adult patients with relapsed CLL in combination with fludarabine and cyclosphosphamide.	**Category 4** Not available as not recommended for use in Scotland
Talimogene laherparepvec (Imlygic®) 10^6 and 10^8 plaque forming units (PFU)/mL solution for injection SMC No 1248/17 https://www.scottishmedicines.org.uk/files/advice/talimogene_laherparepvec_Imlygic_Non_Sub_FINAL_April_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.	**Category 4** Not available as not recommended for use in Scotland
Tenofovir alafenamide (Vemlidy®) 25mg film-coated tablets SMC No 1238/17 https://www.scottishmedicines.org.uk/files/advice/tenofovir_alafenamide_Vemlidy_Non_Sub_FINAL_March_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg).	**Category 4** Not available as not recommended for use in Scotland
Ticagrelor 60mg film-coated tablets (Brilique®) SMC No 1224/17 https://www.scottishmedicines.org.uk/files/advice/ticagrelor_Brilique_FINAL_March_2017_for_website.pdf	**Not recommended** **Indication under review:** co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with a history of myocardial infarction and a high risk of developing an atherothrombotic event.	**Category 4** Not available as not recommended for use in Scotland
Trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla®) SMC No 990/14 https://www.scottishmedicines.org.uk/files/advice/trastuzumab_emtansine_Kadcyla_Resub_FINAL_March_2017_for_website.pdf	**Accepted for use** **Indication under review:** as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy.	**Category 1** Available in line with national guidance

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Desfarasirox 125mg, 250mg, 500mg dispersible tablets (Exjade®) SMC No 347/07 https://www.scottishmedicines.org.uk/files/advice/deferasirox_Exjade_Resub_FINAL_Dec_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias. The current advice relates only to use in the myelodysplastic syndrome (MDS) population. **SMC restriction:** use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate -1 risk.	**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
Dalbavancin 500mg concentrate for solution for infusion (Xydalba®) SMC No 1105/15 https://www.scottishmedicines.org.uk/files/advice/dalbavancin_Xydalba_FINAL_Nov_2015_Updated_08.12.16_1_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. **SMC restriction:** • for second-line use or when meticillin-resistant *Staphylococcus aureus* (MRSA) infection is suspected, or on the advice of local microbiologists or specialists in infectious disease, and • the patient is initially hospitalised due to ABSSSI, requires intravenous antibiotics, but is eligible for early discharge as soon as their medical condition does not require further inpatient treatment.	**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
Buprenorphine 5, 10, 15 and 20 microgram/hour transdermal patch (Butec®) SMC No 1213/17 https://www.scottishmedicines.org.uk/files/advice/buprenorphine_transdermal_patch_Butec_FINAL_Dec_2016_for_website.pdf	Accepted for restricted use **Indication under review:** In adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. **SMC restriction:** for use in elderly patients (over 65 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

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