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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 No 406 - Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/406	**Accepted for use** **Indication under review:** First-line treatment of adults with anaplastic lymphoma kinase (ALK)- positive advanced non-small cell lung cancer (NSCLC). SMC No 1152/16	**10/6/16**	**Yes**
NICE Technology Appraisal Guidance No 407 - Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/407	**Accepted for use** **Indication under review:** Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy. SMC No 1159/16	**10/6/16**	**Yes**
NICE Technology Appraisal Guidance No 408 - Pegaspargase for treating acute lymphoblastic leukaemia	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/408	**Accepted for use** **Indication under review:** as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients. SMC No 1197/16	**7/11/16**	**No**
NICE Technology Appraisal Guidance No 409 - Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/409	**Accepted for use** **Indication under review**: for adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion. SMC No 1074/15	**7/8/15**	**Yes**
NICE Technology Appraisal Guidance No 410 - Talimogene laherparepvec for treating unresectable metastatic melanoma	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/410	No SMC information		**No**

NICE Technology Appraisal Guidance No 411 – Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/411	**Not recommended for use:** **Indication under review**: in combination with gemcitabine and cisplatin chemotherapy for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer who have not received prior chemotherapy for this condition. SMC No 1184/16	**8/7/16**	**No**
NICE Technology Appraisal Guidance No 412 - Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases	**Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/412	**Accepted for use** **Indication under review**: for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. SMC No 1077/15	**4/9/16**	**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
Adalimumab (Humira®) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen Adalimumab (Humira®) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen Adalimumab (Humira®) 40mg/0.8ml vial for paediatric use SMC No 1208/16	**Not recommended for use** **Indication under review:** Treatment of moderately active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies	**Category 4** Not available as not recommended for use in NHS Scotland
Adalimumab (Humira®) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen Adalimumab (Humira®) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen SMC No 1209/16	**Not recommended for use** **Indication under review:** Treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.	**Category 4** Not available as not recommended for use in NHS Scotland
Cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®) SMC No 735/11	**Accepted for restricted use** **Indication review:** cabazitaxel in combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. **SMC restriction:** for use in patients who have received at least 225mg/m^2 (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Canakinumab (Ilaris®) 150mg powder for solution for injection SMC No 1210/16	**Not recommended for use** **Indication under review:** Treatment of active Still's disease including Adult-Onset Still's Disease who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.	**Category 4** Not available as not recommended for use in NHS Scotland
Cefuroxime 50mg powder for solution for injection (Aprokam®) SMC No 932/13	**Accepted for use** **Indication under review:** antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Dequalinium chloride 10mg vaginal tablets (Fluomizin®) SMC No 1194/16	**Accepted for restricted use** **Indication under review:** Treatment of bacterial vaginosis. **SMC restriction:** In patients for whom the initial treatment is not effective or well tolerated.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Fampridine 10mg prolonged-release tablets (Fampyra®) SMC No 789/12	**Not recommended for use** **Indication under review:** For the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS [expanded disability status scale] 4 to 7).	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Fentanyl (Ionsys®) 40 micrograms per dose transdermal system	**Not recommended for use** **Indication under review:** Management of acute moderate to severe post-operative pain in adult patients	**Category 4** Not available as not recommended for use in NHS Scotland
Ferric maltol 30mg hard capsules (Feraccru®) SMC No 1202/16	**Not recommended for use** **Indication under review:** in adults for the treatment of iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD).	**Category 4** Not available as not recommended for use in NHS Scotland
Hydrocortisone 5mg and 20mg modified-release tablets (Plenadren®) SMC No 842/12 **Product Update**	**Not recommended for use** **Indication under review:** Treatment of adrenal insufficiency in adults.	**Category 4** Not available as not recommended for use in NHS Scotland
Idelalisib (Zydelig®) 100-mg, 150-mg film-coated tablets SMC No 1212/16	**Not recommended for use** **Indication under review:** In combination with ofatumumab for the treatment of adult patients with chronic lymphocytic leukaemia: • who have received at least one prior therapy, or • first line treatment in the presence of 17p deletion or TP53 mutation in patients who are not eligible for any other therapies.	**Category 4** Not available as not recommended for use in NHS Scotland
Ivacaftor 150mg film-coated tablets (Kalydeco®) SMC No 1193/16	**Not recommended** **Indication under review:** for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an R117H mutation in the CF transmembrane conductance regulator (CFTR) gene	**Category 4** Not available as not recommended for use in NHS Scotland
Lenalidomide (Revlimid®) 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules SMC No 1211/16	**Not recommended for use** **Indication under review:** Treatment of adult patients with relapsed or refractory mantle cell lymphoma.	**Category 4** Not available as not recommended for use in NHS Scotland
Migalastat, 123mg hard capsules (Galafold®) SMC No 1196/16	**Accepted for restricted use** **Indication under review:** long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation. **SMC restriction:** in males with classic mutations (leucocyte enzyme activity <1%) treatment should commence at diagnosis; in females and those males with later onset mutations with higher levels of leucocyte enzyme activity, treatment should commence when patients experience uncontrolled pain, evidence of renal, cardiac or neurovascular disease, or gastrointestinal symptoms that significantly reduce quality of life.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No 1188/16	**Not recommended for use** **Indication under review:** as monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults.	**Category 4** Not available as not recommended for use in NHS Scotland
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No 1187/16	Accepted for restricted use within NHS Scotland. **Indication under review:** in combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults. **SMC restriction:** for the first-line treatment of advanced melanoma	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Olaparib, 50mg, hard capsules (Lynparza®) SMC No 1047/15 **Re-submission**	**Accepted for use within NHS Scotland.** **Indication under review:** monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed *BRCA*-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Pegaspargase (Oncaspar®) 750U/mL solution for injection/infusion SMC No 1197/16 **Product Update**	**Accepted for use** **Indication under review:** as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1087/15 **Re-submission**	**Not recommended 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 treated with ipilimumab.	**Category 4** Not available as not recommended for use in NHS Scotland
Pertuzumab 420mg concentrate for solution for infusion (Perjeta®) SMC No 1121/16 **Re-submission**	**Not recommended for use** **Indication under review:** For use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.	**Category 4** Not available as not recommended for use in NHS Scotland
Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) 1195/16	Accepted for restricted use **Indication under review:** Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** in patients with genotype 3 (GT3) chronic HCV infection.	**Category 6** Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts

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