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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 |
|---|---|---|---|---|
| **No current technology appraisals for this issue** | | | | |

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 <u>may</u> 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 |
|---|---|---|
| Buprenorphine 5, 10, 15 and 20 microgram/hour transdermal patch (Butec®)<br>SMC No 1213/17 | **Accepted for restricted use**<br>**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.<br>**SMC restriction:** for use in elderly patients (over 65 years). | **<u>Category 6</u>** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2/3/17 |
| Cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®)<br>SMC No 735/11<br>**Resubmission** | **Accepted for restricted use**<br>**Indication under 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.<br>**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. | **<u>Category 1</u> –** Available in line with national guidance |
| Dalbavancin 500mg powder for concentrate for solution for infusion (Xydalba®)<br>SMC No 1105/15 | **Accepted for restricted use**<br>**Indication under review:** treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.<br>**SMC restriction:**<br>• 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<br>• 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. | **<u>Category 6</u>** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2/3/17 |
| Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®)<br>SMC No 1205/17 | **Not recommended**<br>**Indication under review:** as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. | **<u>Category 4</u> –** not available as not recommended for use in NHS Scotland |
| Deferasirox 125mg, 250mg, 500mg dispersible tablets (Exjade®)<br>SMC No 347/07 | **Accepted for restricted use**<br>**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.<br>The current advice relates only to use in the myelodysplastic syndrome (MDS) population<br>**SMC restriction:** use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate - 1 risk. | **<u>Category 6</u>** – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2/3/17 |

| Drug (approved by SMC) | SMC Advice | New Drugs Sub-group Outcome |
|---|---|---|
| Elbasvir 50 mg, grazoprevir 100mg film-coated tablet (Zepatier®)<br>SMC No 1203/17 | **Accepted for use**<br>**Indication under review:** Treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes). | **Category 6 – Not** routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 2/3/17 |
| Eltrombopag (Revolade®) film-coated tablets 25mg and 50mg<br>SMC No 1206/17 | **Accepted for restricted use**<br>**Indication under review:** chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to 17 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).<br>**SMC restriction:** use in patients with severe symptomatic ITP or a high risk of bleeding. | **Category 2** – available in line with local guidance |
| Oestrogens, conjugated, bazedoxifene acetate (Duavive®) 0.45mg / 20mg modified-release tablets<br>SMC No 1220/17 | **Not recommended**<br>**Indication under review:** Treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. | **Category 4 –** not available as not recommended for use in NHS Scotland |
| Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®)<br>SMC No 1204/17 | **Accepted for restricted use**<br>**Indication under review:** The treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) and who have received at least one prior chemotherapy regimen.<br>**SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule. | **Category 1 –** Available in line with national guidance |
| Pertuzumab 420mg concentrate for solution for infusion (Perjeta®)<br>SMC No 1121/16<br>**Resubmission** | **Not recommended**<br>**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 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 |
|---|---|---|---|
| **Gefitinib 250mg film-coated tablets (Iressa®) SMC No 615/10** | **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** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Eribulin (mesilate), 0.44mg/mL solution for injection (Halaven®) SMC No 1065/15** | **Indication under review**: for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. **SMC restriction**: for use in patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated. | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) SMC No 872/13** | **Indication under review**: For the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a nonsteroidal aromatase inhibitor. | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Mepolizumab 100mg powder for solution for injection (Nucala®) SMC No 1149/16** | **Indication under review**: as an add-on treatment for severe refractory eosinophilic asthma in adult patients. SMC restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15 x 109 /L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids. | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 2** – Available in line with local guidance |

| Drug (approved by SMC) | SMC Advice | Previous decision | Updated FV Formulary position |
|---|---|---|---|
| **Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No 1120/16** | **Indication under review**: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. SMC restriction: patients previously untreated with ipilimumab. | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Nivolumab 40mg/4mL and 100mg/10mL vials of concentrate for solution for infusion (Opdivo®) SMC No 1144/16** | **Indication under review:** Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Ibrutinib 140mg hard capsule (Imbruvica®) SMC No 1150/16** | **Indication under review**: Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Ibrutinib 140mg hard capsule (Imbruvica®) SMC No 1151/16** | **Indication under review**: treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.<br>**SMC restriction**: patients with 17p deletion or TP53 mutation who are unsuitable for chemoimmunotherapy. | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |

| Drug (approved by SMC) | SMC Advice | Previous decision | Updated FV Formulary position |
|---|---|---|---|
| **Brivaracetam 10mg, 25mg, 75mg, 100mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®) SMC No 1160/16** | **Indication under review**: Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.<br>**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 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®) SMC No 735/11** | **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.<br>**SMC restriction**: for use in patients who have received at least 225mg/m2 (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 the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Olaparib, 50mg, hard capsules (Lynparza®) SMC No1047/15** | **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 the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No 1187/16** | **Indication under review**: in combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults.<br>SMC restriction: for the first-line treatment of advanced melanoma | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |

| Drug (approved by SMC) | SMC Advice | Previous decision | Updated FV Formulary position |
|---|---|---|---|
| **Migalastat, 123mg hard capsules (Galafold®) SMC No 1196/16** | **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.<br>**SMC restriction**: in males with classic mutations (leucocyte enzyme activity | **Category 6** (not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts) | **Category 1 –** Available in line with national guidance |
| **Pegaspargase (Oncaspar®) 750U/mL solution for injection/infusion SMC No 1197/16** | **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 the ADTC is awaiting 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