

# 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](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>

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## **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
<a href="#">NICE technology appraisal guidance 325 – Nalmefene for reducing alcohol consumption in people with alcohol dependence</a>	<b>Refer to NICE documentation for full guidance</b> <a href="http://www.nice.org.uk/guidance/325">www.nice.org.uk/guidance/325</a>	<b>Accepted for use</b> <b>Indication under review:</b> the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.	7/10/13	<b>No</b>
<a href="#">NICE technology appraisal guidance 326 – Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of NICE technology appraisal guidance 196)</a>	<b>Refer to NICE documentation for full guidance</b> <a href="http://www.nice.org.uk/guidance/326">www.nice.org.uk/guidance/326</a>	<b>Accepted for restricted use</b> <b>Indication under review:</b> adjuvant treatment of adult patients who are at significant risk of relapse following resection of a KIT (CD117) positive gastrointestinal stromal tumour (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. SMC restriction: Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria).	9/4/12	<b>Yes</b>
<a href="#">NICE technology appraisal guidance 327 – Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism</a>	<b>Refer to NICE documentation for full guidance</b> <a href="http://www.nice.org.uk/guidance/327">www.nice.org.uk/guidance/327</a>	<b>Accepted for use</b> <b>Indication under review:</b> treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	13/10/14	<b>No – for continuation if prescribed for a patient from a different Health Board</b>

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
<p>NICE technology appraisal guidance 323 – Erythropoieses – stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142)</p>	<p>Refer to NICE documentation for full guidance <a href="http://www.nice.org.uk/guidance/323">www.nice.org.uk/guidance/323</a></p>	<p><b>Epoetin Theta (Eporatio<sup>®</sup>) – accepted for use</b>  Licensed indication under review: the treatment of symptomatic anaemia associated with chronic renal failure.</p> <p><b>Darbepoetin alfa Sureclick (Aranesp<sup>®</sup>) –</b>  not recommended for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy</p>	<p>12/7/10</p> <p>8/5/06</p>	<p><b>Yes – epoetin delta, epoetin alfa, epoetin beta and epoetin zeta</b></p> <p><b>Yes – darbepoetin alfa</b></p>
<p>NICE technology appraisal guidance 324 – Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88)</p>	<p>Refer to NICE documentation for full guidance <a href="http://www.nice.org.uk/guidance/324">www.nice.org.uk/guidance/324</a></p>	<p><b>Devices are not reviewed by the SMC</b></p>		<p><b>Not applicable</b></p>

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](http://www.scottishmedicines.org)

## Drugs Approved / Not Recommended By SMC

<b>Category 1</b>	Included on the NHS Board formulary for the indication in question
<b>Category 2</b>	Included pending protocol
<b>Category 3</b>	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
<b>Category 4</b>	Not included on the NHS Board Formulary because clinicians do not support the formulary inclusion
<b>Category 5</b>	Not included on the NHS Board Formulary because clinicians have not responded to an invitation to apply for formulary inclusion to this medicine
<b>Category 6</b>	Not included pending protocol

The ADTC recommends that prescribers may prescribe these drugs in accordance with SMC advice.

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Abiraterone acetate, 250mg tablets (Zytiga <sup>®</sup> )	<b>Not recommended</b> <b>Indication under review:</b> with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	<b>Not recommended by SMC therefore not included on the formulary</b>
Aztreonam lysine, 75mg powder and solvent for nebulizer solution (Cayston <sup>®</sup> ) <b>Resubmission</b>	<b>Accepted for restricted use</b> <b>Indication under review:</b> suppressive therapy of chronic pulmonary infections due to pseudomonas aeruginosa in patients with cystic fibrosis aged six years and older. <b>SMC restriction:</b> when inhaled colistimethate sodium and inhaled tobramycin are not tolerated or nor providing satisfactory therapeutic benefit (measured as $\geq 2\%$ decline in forced expiratory volume in 1 second [FEV <sub>1</sub> ])	<b>Category 6</b>
Bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin <sup>®</sup> ) <b>Resubmission</b>	<b>Not recommended</b> <b>Indication under review:</b> in combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.	<b>Not recommended by SMC therefore not included on the formulary</b>
Bosutinib 100mg, 500mg film coated tablets (Bosulif <sup>®</sup> )	<b>Accepted for use</b> <b>Indication under review:</b> treatment of adult patients with chronic phase (CP), accelerated phase (AP) and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.	<b>Category 6</b>
Brimonidine, 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso <sup>®</sup> )	<b>Accepted for restricted use</b> <b>Indication under review:</b> the symptomatic treatment of facial erythema of rosacea in adult patients. <b>SMC restriction:</b> for use in patients with moderate to severe persistent facial erythema associated with rosacea.	<b>Category 1</b>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediate-release tablets (Vokanamet <sup>®</sup> )	<p><b>Accepted for restricted use</b></p> <p><b>Indication under review:</b> in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:</p> <ul style="list-style-type: none"> <li>• In patients not adequately controlled on their maximally tolerated doses of metformin alone;</li> <li>• In patients on their maximally tolerated doses of metformin along with other glucose-lowering medicinal products, including insulin, when these do not provide adequate glycaemic control;</li> <li>• In patients already being treated with the combination of canagliflozin and metformin as separate tablets.</li> </ul> <p><b>SMC restriction:</b> use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy.</p>	<b>Category 1</b>
Cetuximab, 100mg/20mL and 500mg/100mL solution for infusion (Erbix <sup>®</sup> )	<p><b>Accepted for restricted use</b></p> <p><b>Indication under review:</b> treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer:</p> <ul style="list-style-type: none"> <li>• In combination with irinotecan-based chemotherapy</li> <li>• In first-line in combination with FOLFOX;</li> <li>• As a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan</li> </ul> <p><b>SMC restriction:</b> for use in patients with RAS wild-type metastatic colorectal cancer, in combination with irinotecan or oxaliplatin-based chemotherapy, in patients who have not previously received chemotherapy for their metastatic disease (first-line treatment).</p>	<b>Category 6</b>
Colestilan 1g film-coated tablets, 2g and 3g granules sachets (BindRen <sup>®</sup> )	<p><b>Not recommended</b></p> <p><b>Indication under review:</b> treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.</p>	<b>Not recommended by SMC therefore not included on the formulary</b>
Follitropin alfa 75units, 150units, 225units, 300units, 450units pre-filled pen for subcutaneous injection (Bemfola <sup>®</sup> )	<p><b>Accepted for use</b></p> <p><b>Indication under review:</b> In adult women for:</p> <ul style="list-style-type: none"> <li>• Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate.</li> <li>• Stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.</li> <li>• In association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and follicle-stimulating hormone (FSH) deficiency. In clinical trials these patients were defined by an endogenous serum LH level &lt;1.2 units/L.</li> </ul>	<b>Category 4</b>
Olodaterol 2.5 microgram solution for inhalation (Striverdi <sup>®</sup> Respimat <sup>®</sup> )	<p><b>Accepted for use</b></p> <p><b>Indication under review:</b> maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.</p>	<b>Category 6</b>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Omalizumab 150mg solution for injection (Xolair®)	<p><b>Accepted for restricted use</b></p> <p><b>Indication under review:</b> as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.</p> <p><b>SMC restriction:</b> use in adults and adolescents with chronic spontaneous urticaria who have an inadequate response to combination therapy with H1 antihistamines, leukotriene receptor antagonists (LTRA) and H2 antihistamines, used according to current treatment guidelines.</p>	Category 1
Paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®)	<p><b>Accepted for restricted use</b></p> <p><b>Indication under review:</b> in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.</p>	Category 6
Peginterferon 63, 94 and 125 microgram solution for injection in pre-filled syringe (Plegridy®)	<p><b>Accepted for use</b></p> <p><b>Indication under review:</b> in adult patients for the treatment of relapsing remitting multiple sclerosis.</p>	Category 1
Umeclidinium/vilanterol, 55/22 micrograms, inhalation powder (Anoro®)	<p><b>Accepted for use</b></p> <p><b>Indication under review:</b> as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.</p>	Category 6

## Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Cholecalciferol 25,000 international units oral solution (InVita D3 <sup>®</sup> )	<b>Accepted for use</b> <b>Indication under review:</b> the prevention and treatment of Vitamin D deficiency.	Category 2 20/11/15	Category 1
Empagliflozin 10mg and 25mg tablets (Jardiance <sup>®</sup> )	<b>Accepted for restricted use</b> <b>Indication under review:</b> treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy: in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. <b>SMC restriction:</b> to use in the following situations: <ul style="list-style-type: none"> <li>• Dual therapy in combination with metformin, when a sulphonylurea is inappropriate.</li> <li>• Triple therapy in combination with metformin plus standard of care.</li> <li>• Add-on to insulin therapy in combination with insulin plus standard of care.</li> </ul>	Category 6 25/9/14	Category 1
Posaconazole 100mg gastro resistant tablets (Noxafi <sup>®</sup> )	<b>Accepted for restricted use</b> <b>Indication under review:</b> in the treatment of the following fungal infections in adults: <ul style="list-style-type: none"> <li>- Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;</li> <li>- Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B;</li> <li>- Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant to itraconazole;</li> <li>- Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.</li> </ul> For prophylaxis of invasive fungal infections	Category 6 25/9/14	Category 4

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

