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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, 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.

The SMC has advised that the following drugs are **not** recommended for use in NHS Scotland.

| Generic Name & Formulation | Brand Name | Indication |
|---|---|---|
| Abiraterone 250mg tablets | *Zytiga*® | Zytiga is indicated 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. |
| Axitinib 1mg and 5mg film-coated tablet | *Inlyta*® | For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. |
| Bevacizumab, 25mg/mL, concentrate for solution for infusion | *Avastin*® | Bevacizumab, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelian ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. |
| Botulinum toxin type A, 50 unit, 100 unit and 200 unit powder for solution for injection **Resubmission** | *Botox*® | The prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine. |
| Crizotinib, 200mg and 250mg, hard capsule | *Xalkori*® | Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) |
| Deferasirox 125mg, 250mg and 500mg dispersible tablets | *Exjade*® | Treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is |

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| | | contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older |
| Insulin degludec 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen | *Tresiba®* | Treatment of diabetes mellitus in adults |
| Mannitol, 400mg, inhalation powder, hard capsule | *Bronchitol®* | Treatment of cystic fibrosis (CF) in adults aged 18 years and above as add-on therapy to best standard of care. |
| Rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride film-coated tablets | *Voractiv®* | Initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines. |
| Ruxolitinib 5mg, 15mg and 20mg tablets | *Jakavi®* | Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also know as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. |
| Tafamidis meglumine 20mg soft capsules | *Vyndaqel®* | Treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment. |
| Timothy grass pollen allergen 75,000 SQ-T oral lyophilisate | *Grazax®* | Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years and older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen. |
| Vildagliptin/metformin hydrochloride 50mg/850mg and 50mg/1000mg film-coated tablets | *Eucreas®* | Treatment of type 2 diabetes mellitus:<br>• In combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea<br>• In triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. |

## 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 Quality Improvement Scotland (NHS QIS) reviews MTAs and decides whether the recommendations should apply in Scotland where Health 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 (Single) Technology Appraisal Guidance No 268 – Ipilimumab for previously treated advanced (unresectable or metastatic) melanoma** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA268 | **Not recommended** **Indication under review** – treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy | **6/5/12** | **No** |
| **NICE (Single) Technology Appraisal Guidance No 269 – Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA269 | **Not recommended** **Indication under review** – as monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma | **10/8/12** | **No** |
| **NICE (Single) Technology Appraisal Guidance No 270 – Decitabine for the treatment of acute myeloid leukaemia (terminated appraisal)** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA270 | **Not recommended** **Indication under review** – treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction therapy | **7/12/12** | **No** |
| **NICE (Single) Technology Appraisal Guidance No 271 – Fluocinolone acetonide intravitreal implants for chronic diabetic macular oedema** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA271 | **On SMC work Programme – advice due May 2013** | | **No – has not been through the SMC process yet** |
| **NICE (Single) Technology Appraisal Guidance No 272 – Vinflunine for the treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA272 | **Not recommended** **Indication under review** – monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract (TCCU) after failure of a prior platinum-containing regimen | **7/3/11** | **No** |
| **NICE (Single) Technology Appraisal Guidance No 273 – Tadalafil for the treatment of symptoms associated with benign** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA273 | **Not recommended** **Indication under review** – treatment of the signs and symptoms of benign prostatic hyperplasia in adult males | **14/1/13** | **Yes – under section 7.4.5 – Drugs for impotence** |

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|---|---|---|---|---|
| **prostatic hyperplasia (terminated appraisal)** | | | | |

| 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 (Single) Technology Appraisal Guidance No 274 – Ranibizumab for treating diabetic macular oedema (rapid review of technology appraisal guidance 237)** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA274 | **Accepted for restricted use**<br>**Indication under review –** for the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO)<br>**SMC restriction** – restricted to use in patients with macular oedema secondary to central vein occlusion (CRVO) | **7/10/11** | **Yes** |
| **NICE (Single) Technology Appraisal Guidance No 275 – Apixaban for preventing stroke and systemic embolism in people with nonvalvular atrial fibrillation** | **Refer to NICE documentation for full guidance** www.nice.org.uk/guidance/TA275 | **Accepted for use**<br>**Indication under review –** for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial firbrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II) | **11/1/13** | **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**

## Drugs Approved By SMC

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 |
|---|---|---|
| Abatacept 250mg powder for concentrate *for solution for infusion (Orencia®)* **Resubmission** | **Accepted for restricted use**<br>**Indication under review:** in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor. | **Pending awaiting outcome of discussions with rheumatologists** |
| Adalimumab, 40mg/0.8mL, solution for injection *(Humira®)* | **Accepted for use**<br>**Indication under review:** treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs) | **Pending awaiting outcome of discussions with rheumatologists** |
| Aflibercept 40mg/mL solution for intravitreal injection *(Eylea®)* | **Accepted for use**<br>**Indication under review:** in adults for the treatment of neovascular (wet) age-related macular degeneration | **Not included in the formulary** |

| Drug (approved by SMC) | SMC Advice | New Drugs Sub-group Outcome |
|---|---|---|
| Apixaban 2.5mg and 5mg film-coated tablets *(Eliquis®)* | **Accepted for restricted use**<br><br>**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 prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class≥II) | **Not included in the formulary** |
| Clostridium botulinum type A toxin-haemagglutin complex 300 units and 500 units *(Dysport®)* **Re-submission** | **Accepted for restricted use**<br><br>**Indication Under review**: for focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy<br><br>**SMC restriction**: for focal spasticity of the upper limbs associated with stroke | **Included in the formulary** |
| Colecalciferol 800 international units (equivalent to 20 micrograms vitamin $D_3$) tablets *(Desunin 800 IU®)* **Product Update** | **Accepted for restricted use**<br><br>**Indication Under review**: prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered | **Included in the formulary – no brand will be specified** |
| Etanercept 10mg and 25mg powder and solvent for solution for injection for paediatric use, 25mg and 50mg solution for injection in pre-filled syringe, 50mg solution for injection in pre-filled pen *(Enbrel®)* **Product Update** | **Accepted for restricted use**<br><br>**Indication Under review**: for the treatment of<br>• Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate;<br>• Psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate;<br>• Enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate<br><br>**SMC restriction**: use within specialist rheumatology services (including those working within the network for paediatric rheumatology). | **Included in the formulary** |
| Ferumoxytol, 30mg/mL solution for injection *(Rienso®)* | **Accepted for restricted use**<br><br>**Indication Under review**: intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease<br><br>**SMC restriction:** treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used | **Not included in the formulary** |
| Infliximab 100mg powder for concentrate for solution for infusion *(Remicade®)* | **Accepted for restricted use**<br><br>**Indication Under review**: treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.<br><br>**SMC restriction:** as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory | **Included in the formulary** |

| Drug (approved by SMC) | SMC Advice | New Drugs Sub-group Outcome |
|---|---|---|
| Ingenol mebutate, 150 & 500micrograms/g, gel *(Picaro®)* | **Accepted for use**<br><br>**Indication under review:** Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults. | **Included in the formulary** |
| Insulin glargine 100units/ml solution for injection in a vial, cartridge, pre-filled pen (*Lantus®, Clikstar®, Lantus®Solostar®)* | **Accepted for restricted use**<br><br>**Indication Under review**: treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above<br><br>**SMC restriction:** patients in whom treatment with an insulin analogue is appropriate | **Included in the formulary** |
| Ipilimumab 5mg/mL concentrate for *solution for infusion (Yervoy®)*<br>**Resubmission** | **Accepted for use**<br><br>**Indication under review:** treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy | **Included in the formulary. Used in line with the West of Scotland Cancer Network Protocols** |
| Linagliptin 2.5mg plus metformin 850mg and linagliptin 2.5mg plus metformin 1000mg film-coated tablets (*Jentadueto®)*<br>**Product Update** | **Accepted for restricted use**<br><br>**Indication Under review:** treatment of adult patients with type 2 diabetes mellitus:<br>• As an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin<br>• In combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea<br><br>**SMC restriction:** to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and these fixed-doses are considered appropriate | **Included in the formulary** |
| Linagliptin, 5mg film-coated tablets *(Trajenta®)* | **Accepted for restricted use**<br><br>**Indication Under review:** the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:<br><br>**as monotherapy**<br>• In patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment<br><br>**as combination therapy**<br>• In combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products does not provide adequate glycaemic control.<br>• In combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control<br><br>**SMC restriction**:<br>• As monotherapy in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance<br>• As combination therapy with a sulphonylurea and metformin when diet and exercise plus dual therapy does not provide adequate glycaemic control | **Included in the formulary** |

| Drug (approved by SMC) | SMC Advice | New Drugs Sub-group Outcome |
|---|---|---|
| Lisdexamfetamine dimesylate 30mg, 50mg and 70mg capsules (Elvanse®) | **Accepted for use**<br><br>**Indication Under Review:** as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate | **Pending awaiting outcome of discussions at the Primary Care DTC** |
| Mirabegron 25mg and 50mg prolonged-release tablets (Betmiga®) | **Accepted for use**<br><br>**Indication under review:** for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome. | **Included in the formulary for specialist initiation only** |
| Palonosetron 500 micrograms soft capsule *(Aloxi®)*<br>**Product Update** | **Accepted for restricted use**<br><br>**Indication Under review**: prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults | **Not included in the formulary** |
| Ranibizumab, 10mg/mL solution for injection (Lucentis®)<br>**Resubmission** | **Accepted for use**<br><br>**Indication Under review:** for the treatment of visual impairment due to macular oedema (MO) secondary to branch retinal vein occlusion (BRVO) in adults | **Pending** |
| Rivaroxaban 15mg and 20mg film-coated *tablets (Xarelto®)* | **Accepted for use**<br><br>**Indication Under review:** treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults | **Included in the formulary** |
| Sugammadex 100mg/mL (1mL, 2mL, 5mL) solution for injection *(Bridion®)*<br>**Resubmission** | **Accepted for restricted use**<br><br>**Indication under review:** reversal of neuromuscular blockade induced by rocuronium or vercuronium. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents. This resubmission is for part of the indication relating to routine reversal of neuromuscular blockade.<br><br>**SMC restriction:** only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/chest surgery) or where prompt reversal of neuromuscular block is required. | **Pending – awaiting discussions with the anaesthetists for this additional indication** |
| Ulipristal acetate, 5mg tablet *(Esmya®)* | **Accepted for restricted use**<br><br>**Indication Under review:** pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months | **Not included in the formulary** |

**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