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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 (Single) Technology Appraisal Guidance No 303 – Teriflunomide for treating relapsing – remitting Multiple Sclerosis	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/303**	**Accepted for restricted use** **Indication under review**: treatment of adults with relapsing remitting multiple sclerosis (MS). **SMC restriction**: as an alternative to treatment with interferon beta of glatiramer acetate. Teriflunomide is not expected to be used for the treatment of patients with highly active disease.	**7/2/14**	**Yes**
NICE (Single) Technology Appraisal Guidance No 305 – Aflibercept for treating visual impairment caused by macular oedema secondary to central vein occlusion	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/305**	**Accepted for use** **Indication under review:** for adults for the treatment of visual impairment due to macular oedema secondary to central vein occlusion.	**7/3/14**	**Decision pending**
NICE (Single) Technology Appraisal Guidance No 306 – Pixantrone monotherapy for treating multiply relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/306**	No SMC submission for this product.	**N/A**	**N/A**

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No

No Multiple Technology Appraisals

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 / Not Recommended By SMC

Category 1	Included on the NHS Board formulary for the indication in question
Category 2	Included pending protocol
Category 3	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
Category 4	Not included on the NHS Board Formulary because clinicians do not support the formulary inclusion
Category 5	Not included on the NHS Board Formulary because clinicians have not responded to an invitation to apply for formulary inclusion to this medicine
Category 6	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
Adapalene 0.1% benzoyl peroxide 2.5% gel (Epiduo®)	**Accepted for restricted use** **Indication under review:** cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. **SMC restriction**: the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate.	**Category 1**
Afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®)	**Accepted for use** **Indication under review:** as monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naive adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s).	**Category 2** **Protocol will be developed by West of Scotland Cancer Network**
Aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®) **Resubmission**	**Accepted for use** **Indication under review:** in combination with irinotecan/5-fluorouracil/folinic acid (FOLFORI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.	**Category 2** **Protocol will be developed by West of Scotland Cancer Network**
Aflibercept, 40mg/mL solution for injection (Eylea®)	**Accepted for use** **Indication under review:** for adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.	**Category 6**
Alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®)	**Not recommended** **Indication under review:** for adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.	**Not recommended by SMC therefore not included in the formulary**
Azithromycin 500mg powder for solution for infusion (Zedbac®)	**Accepted for use** **Indication under review:** the treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required.	**Category 6**
Colestilan 1g film-coated tablet, 2g and 3g granules sachet (BindRen®)	**Not recommended** **Indication under review:** treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	**Not recommended by SMC therefore not included in the formulary**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®) **Resubmission**	**Accepted for restricted use** **Indication under review:** for use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction**: in combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control.	**Category 1**
Darunavir 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) **Product Update**	**Accepted for restricted use** **Indication under review:** darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients 12 to 17 years of age and at least 40kg body weight who are: antiretroviral therapy (ART) naive; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm^3. **SMC restriction**: in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV.	**Category 1** **To be included for continuation of therapy from a specialist centre**
Dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules. (Tecfidera®)	**Accepted for use** **Indication under review:** treatment of adult patients with relapsing remitting multiple sclerosis.	**Category 2** **Protocol will be developed by Neurology Service**
Fluocinolone acetonide intravitreal 190 microgram intravitreal implant (Illuvien®) **Resubmission**	**Accepted for restricted use** **Indication under review:** treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. **SMC restriction:** • only in patients in whom the affected eye is pseudophakic (has an artificial lens after cataract surgery and; • retreatment would take place only if the patients had previously responded to treatment with fluocinolone acetonide and subsequently best corrected visual acuity had deteriorated to less than 20/32	**Category 6**
Fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar Ellipta®)	**Accepted for restricted use** **Indication under review:** symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with forced expiratory volume 1 second (FEV_1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. **SMC restriction**: in patients with severe COPD (FEV_1 <50% predicted normal)	**Category 6**
Insulin degludec 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen (Tresiba®)	**Not recommended** **Indication under review:** treatment of diabetes mellitus in adults.	**Not recommended by SMC therefore not included in the formulary**
Lenalidomide 2.5mg, 5mg, and 10mg, hard capsules (Revlimid®)	**Accepted for use** **Indication under review:** for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenic abnormality when other therapeutic options are insufficient or inadequate.	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Lenalidomide 7.5mg, 10mg, 15mg and 25mg, hard capsules (Revlimid®) **Resubmission**	**Accepted for restricted use** **Indication under review:** in combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy). **SMC restriction**: to use at first relapse in patients who have received prior therapy with bortezomib in whom thalidomide has not been tolerated or is contraindicated.	**Category 2** **Protocol will be developed by West of Scotland Cancer Network**
Levonorgestrel 1500microgram tablet (Upostelle®) **Product Update**	**Accepted for use** **Indication under review:** emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.	**Category 1**
Lipegfilgrastim, 6mg, solution for injection (Lonquex®)	**Accepted for restricted use** **Indication under review:** reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). **SMC restriction**: where a long-acting granulocyte-colony-stimulating factor is appropriate.	**Category 2** **Protocol will be developed by West of Scotland Cancer Network**
Lomitapide 5mg, 10mg, 20mg hard capsules (Lojuxta®)	**Not recommended** **Indication under review:** Adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis in adult patients with homozygous familial hypercholesterolaemia (HoFH).	**Not recommended by SMC therefore not included in the formulary**
Macitentan, 10mg film-coated tablets (Opsumit®)	**Accepted for restricted use** **Indication under review:** as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension in adult patients of World Health Organisation Functional Class II to III.	**Category 1 Included on the formulary for continuation of therapy from a specialist centre**
Rilpivirine 25mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®)	**Accepted for use** **Indication under review:** treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emticitabine, and with viral load <100,000 HIV-1 RNA copies/mL. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®.	**Category 1**
Saxagliptin 2.5mg & 5mg film-coated tablets (Onglyza®)	**Not recommended** **Indication under review:** monotherapy in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.	**Not recommended by SMC therefore not included in the formulary**
Solifenacin succinate plus tamsulosin hydrochloride 6mg/0.4mg modified release tablet (Vesomni®) **Product Update**	**Accepted for use** **Indication under review:** for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Teriflunomide, 14mg, film-coated tablets (Aubagio®)	**Accepted for restricted use** **Indication under review:** treatment of adults with relapsing remitting multiple sclerosis (MS). **SMC restriction**: as an alternative to treatment with interferon beta or glatiramer acetate, Teriflunomide is not expected to be used for the treatment of patients with highly active disease.	**Category 2** **Protocol will be developed by Neurology Service**
Timolol, 1mg/g eye gel for single-dose container (Tiopex®) **Product Update**	**Accepted for restricted use** **Indication under review:** reduction of the elevated intraocular pressure in patients with; - ocular hypertension - Chronic open angle glaucoma **SMC restriction**: to use in patients who have proven sensitivity to preservatives	**Category 1**
Ustekinumab 45mg solution for injection in pre-filled syringe (Stelara®)	**Accepted for restricted use** **Indication under review**: alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate. **SMC restriction**: for use in patients with active psoriatic arthritis who have failed on, or are unsuitable for, treatment with an anti-TNF drug.	**Category 1**
Zonisamide 25mg, 50mg and 100mg capsules (Zonegran®) **Product Update**	**Accepted for restricted use** **Indication under review:** as adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above. **SMC restriction**: on advice from specialists (paediatric neurologists or paediatricians with an expertise in epilepsy).	**Category 1**

Changes on previous ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Eltrombopag, 25mg, 50mg, 75mg film-coated tablets (Revolade®)	**Accepted for use** **Indication under review**: in adult patients with chronic hepatitis C virus infection, for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.	**Category 6** **19/12/13**	**Category 1**
Nalmefene 18mg film-coated tablets (Selincro®)	**Accepted for use** **Indication under review**: 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.	**Category 2** **24/10/13**	**Category 4**

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Mannitol 40mg inhalation powder hard capsule (Bronchitol®)	**Accepted for restricted use** **Indication under review:** treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. **SMC restriction**: as an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining liver function and in whom other osmotic agents are considered unsuitable.	**Category 6** **19/12/13**	**Category 1** **Comment – continuation of therapy from a specialist centre**
Bortezomib 3.5mg powder for solution for injection (Velcade®)	**Accepted for restricted use** **Indication under review:** in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematogenic stem cell transplantation. **SMC restriction**: use as triple therapy in combination with dexamethasone and thalidomide.	**Category 6** **19/12/13**	**Category 2** **Protocol will be developed by West of Scotland Cancer Network**
Vemurafenib 240mg film-coated tablet (Zelboraf®)	**Accepted for restricted use** **Indication under review**: as monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. **SMC restriction:** for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma.	**Category 6** **19/12/13**	**Category 2** **Protocol will be developed by West of Scotland Cancer Network**
Enzalutamide 40mg capsules (Xtandi®)	**Accepted for use** **Indication under review:** treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy.	**Category 6** **24/10/13**	**Category 1**
Axitinib, 1mg and 5mg film-coated tablets (Inlyta®)	**Accepted for use** **Indication under review:** for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.	**Category 6** **24/10/13**	**Category 1**
Crizotinib 200mg and 250mg, hard capsule (Xalkion®)	**Accepted for use** **Indication under review:** treatment of adults with previously treated anaplastic Lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	**Category 6** **24/10/13**	**Category 1**
Granisetron 3.1mg / 24hours transdermal patch (Sancuso®)	**Accepted for use** **Indication under review:** in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult.	**Category 6** **24/10/13**	**Category 4** **Any requests would be through the non-formulary process**

Dapagliflozin

The formulary advice for Dapagliflozin has been changed to prescribable in primary care by those experienced in managing diabetes and according to SMC restriction outlined below.

SMC restriction: “Dapagliflozin is restricted to use as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate. Also In combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control.”

The electronic formulary will be updated to reflect this.

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