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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 – 345 Naloxegol for treating opioid-induced constipation	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/345**	**Forthcoming submission** **Indication:** treatment of opioid induced constipation in patients who have had an inadequate response to laxative(s).	**Advice due 7/12/15**	No
NICE technology appraisal guidance - 346 Aflibercept for treating diabetic macular oedema	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/346**	**Accepted for restricted use** **Indication under review**: for adults for the treatment of visual impairment due to diabetic macular oedema (DMO). **SMC restriction**: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Diabetic Retinopathy Study (ETDRS) letters or less at baseline.	10/11/14	Yes
NICE technology appraisal guidance - 347 Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/347**	**Accepted for use** **Indication under review**: in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy. Addition of nintedanib to second-line treatment of stage IIIb/IV NSCLC with docetaxel significantly increased overall survival in the subgroup patients with adenocarcinoma tumour histology.	13/4/15	No
NICE technology appraisal guidance – 348 Everolimus for preventing organ rejection in liver transplantation	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/348**	**Not been through the SMC for this indication**		Yes
NICE technology appraisal guidance - 349 Dexamethasone intravitreal implant for treating diabetic macular oedema	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/349**	**Accepted for use** **Indication under review:** treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.	11/5/15	Yes
NICE technology	**Refer to NICE**	**Accepted for restricted use**	8/6/15	Yes

appraisal guidance - 350 Secukinumab for treating moderate to severe plaque psoriasis	**documentation for full guidance www.nice.org.uk/guidance/350**	**Indication under review**: treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.		
NICE technology appraisal guidance - 352 Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/352**	**Accepted for restricted use** **Indication under review**: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor- alpha (TNFα) antagonist. **SMC restriction:** for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNFα antagonist.	13/7/15	No
NICE technology appraisal guidance - 354 Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/354**	**Forthcoming submission**: advice due November 2105	Not applicable	
NICE technology appraisal guidance – 355 Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/355**	**Forthcoming submission**: advice due November 2105	Not applicable	

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 were reviewed

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, unless they are not recommended by SMC

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Abiraterone acetate 250mg tablets (Zytiga®) SMC No 873/13 **Independent Review Panel**	**Indication under review:** abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	**Category 2**
Adalimumab 40mg/0.8ml solution injection (Humira®) SMC No 1068/15 **Product Update**	**Accepted for restricted use** **Indication under review:** treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. **SMC restrictions**: patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score ≥10 and a Dermatology Life Quality Index (DLQI) OF >10	**Category 1**
Aflibercept 40mg/mL solution for injection (Eylea®) SMC No 1074/15	**Accepted for use.** **Indication under review:** for adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.	**Category 1**
Avanafil 50mg, 100mg, 200mg tablets (Spedra®) SMC No 980/14	**Not recommended.** **Indication under review:** Treatment of erectile dysfunction (ED) in adult men. In order for avanafil to be effective, sexual stimulation is required.	**Not recommended by SMC therefore not included in the formulary**
Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) SMC No 1063/15	**Accepted for restricted use.** **Indication under review:** in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents. **SMC restriction:** to use in combination with paclitaxel.	**Category 2**
Bortezomib 3.5mg powder for solution for injection (Velcade®) SMC No 1075/15	**Accepted for use.** **Indication under review:** in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.	**Category 1**
Budesonide 9mg prolonged release tablets (Cortiment®) SMC No 1093/15 **Product Update**	**Not recommended** **Indication under review:** in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient.	**Not recommended by SMC therefore not included in the formulary**
Ceftobiprole, 500mg powder for concentrate for solution for infusion (Zevtera®) SMC No 943/14 **Resubmission**	**Accepted for restricted use** **Indication under review:** Ceftobiprole is indicated for the treatment of the following infections in adults: • Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) • Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents. **SMC restriction**: for use in the treatment of HAP (excluding VAP) when activity is required against suspected methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative pathogens (including *Pseudomona aeruginosa*, *Escherichia coli* and *Klebsielle pneumoniae*) and when combination treatment that included vancomycin or teicoplanin is inappropriate or has not been tolerated or when treatment modification is required, i.e. as an alternative to linezolid-based regimens	**Category 6**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®) SMC No 1089/15	**Accepted for use** **Indication under review:** treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.	**Category 6**
Darunavir 75mg, 150mg, 400mg, 600mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) SMC No 1069/15 **Product Update**	**Accepted for restricted use** **Indication under review:** once daily 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 aged 3 to 12 years and ≥15kg who are 1) Treatment-naïve 2) Treatment-experienced with no darunavir resistance-associated mutations, plasma-HIV-1 RNA <100,000 COPIES/mL, and CD4+ count >100x10^6 cells/L. **SMC restrictions**: to be prescribed under the supervision of specialists in paediatric HIV.	**Category 1**
Darunavir 800mg, cobicistat 150mg film-coated tablet (Rezolsta®) SMC No 1081/15	**Accepted for use** **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use.	**Category 1**
Elosulfase alfa, 1mg/mL concentrate for solution for infusion (Vimizin®) SMC No 1072/15	**Not recommended.** **Indication under review:** treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages.	**Not recommended by SMC therefore not included in the formulary**
Empagliflozin plus metformin 5mg/85mg, 5mg/1000mg, 12.5mg/850mg, 12.5mg/1000mg film-coated tablets (Synjardy®) SMC No 1092/15 **Product Update**	**Accepted for restricted use** **Indication under review:** in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control; • in patients inadequately controlled on their maximally tolerated dose of metformin alone • in patients inadequately controlled with metformin in combination with other glucose-lowering medicinal products, including insulin • in patients already being treated with the combination of empagliflozin and metformin as separate tablets. **SMC restriction:** • for use in patients for whom this fixed dose combination of empagliflozin and metformin is considered appropriate. for use as dual therapy (empagliflozin and metformin) when a sulphonylurea is inappropriate.	**Category 1**
Enzalutamide, 40mg soft capsules (Xtandi®) SMC No 1066/15	**Not recommended** **Indication under review:** treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	**Not recommended by SMC therefore not included in the formulary**
Eribulin (mesilate), 0.44mg/mL, solution for injection (Halaven®) SMC No 1065/15	**Not recommended** **Indication under review:** for the treatment of 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.	**Not recommended by SMC therefore not included in the formulary**
Everolimus 2.5mg, 5mg and 10mg tablet (Afinitor®) SMC No 872/13 **Resubmission**	**Not recommended** **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 non-steroidal aromatase inhibitor.	**Not recommended by SMC therefore not included in the formulary**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Insulin degludec/ liraglutide 100units/mL / 3.6mg/mL solution for injection pre-filled pen (Xultophy®) SMC No 1088/15	**Accepted for restricted use** **Indication under review:** Treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with a GLP-1 receptor agonist or with basal insulin do not provide adequate glycaemic control. **SMC restriction:** for use in patients who are uncontrolled on basal insulin analogues (*glycosylated* haemoglobin [HbA1c] >7.5% [59mmol/mol]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin to obtain glucose control.	**Category 6**
Insulin Glargine 300 units/mL solution for injection in a pre-filled pen (Toujeo®) SMC No 1078/15	**Accepted for restricted use.** **Indication under review:** Treatment of type 1 or type 2 diabetes mellitus in adults aged 18 years and above. **SMC restriction:** Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections.	**Category 1**
Ketoconazole 200mg tablets (Ketaconazole HRA®) SMC No 1100/15	**Not recommended for use.** **Indication under review:** Treatment of endogenous Cushing's syndrome in adults and adolescents above the age of 12 years.	**Not recommended by SMC therefore not included in the formulary**
Ledipasvir/sofosbuvir 90mg/400mg film-coated tablet (Harvoni®) SMC No 1084/15	**Accepted for restricted use.** **Indication under review:** Treatment of genotype 3 chronic hepatitis C (CHC) in adults. **SMC restriction:** patients who are ineligible for or unable to tolerate interferon.	**Category 1**
Lisdexamfetamine dimesylate, 30mg, 50mg and 70mg hard capsules (Elvanse Adult®) SMC No 1079/15	**Accepted for use.** **Indication under review:** as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults. Based on clinical judgment, patients should have ADHD of at least moderate severity.	**Category 1**
Magnesium aspartate dehydrate equivalent to 243mg (10mmol) of magnesium powder for oral solution (Magnaspartate®) SMC No 1042/15 **Product Update**	**Accepted for use** **Indication under review**: for the prevention of magnesium deficiency, as diagnosed by a doctor.	**Category 1**
Midodrine hydrochloride 2.5mg, 5mg tablets (Bramox®) SMC No 1094/15 **Product Update**	**Accepted for use** **Indication under review:** in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.	**Category 1**
Nintedanib 100mg and 150mg capsules (Ofev®) SMC No 1076/15	**Accepted for restricted use** **Indication under review:** in adults for the treatment of idiopathic pulmonary fibrosis (IPF). **SMC restriction:** For use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.	**Category 2**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Olaparib 50mg hard capsules (Lynparza®) SMC No 1047/15 **Not recommended**	**Not recommended** **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.	**Not recommended by SMC therefore not included in the formulary**
Palonosetron, 250 micrograms solution for injection (Aloxi®) SMC No 1073/15	**Accepted for use** **Indication under review**: prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, in paediatric patients 1 month of age and older.	**Category 6**
Panitumumab (Vectibix®) SMC No 1082/15 **Not recommended**	**Not recommended** **Indication under review:** treatment of adult patients with wild-type RAS metastatic colorectal cancer first-line in combination with FOLFIRI.	**Not recommended by SMC therefore not included in the formulary**
Pasireotide (as pamoate), 20mg, 40mg 60mg powder and solvent for suspension for injection (Signifor®) SMC No 1048/15	**Accepted for use.** **Indication under review:** Treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue.	**Category 1**
Posaconazole 300mg concentrate for solution for infusion (Noxafil®) SMC No 1067/15 **Product Update**	**Accepted for use** **Indication under review**: • Invasive aspergillosis in patients with disease that is refractory to amphoteracin B or itraconazole or in patients who are intolerant of these medicinal products • Fusariosis in patients with disease that is refractory to amphoteracin B or in patients who are intolerant of amphoteracin B • Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole • Coccidioidomycosis in patients with disease that is refractory to amphoteracin B, Itraconazole or fluconazole or in patients who are intolerant of these medicinal products For prophylaxis of invasive fungal infections (IFI) in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing IFI Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high risk of developing IFI	**Category 1**
Radium-223 dichloride 1000kBq/mL solution for injection (Xofigo®) SMC No 1077/15	**Accepted for use** **Indication under review:** for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.	**Category 6**
Riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film coated tablets (Adempas®) SMC No 1056/15	**Accepted for use** **Indication under review:** pulmonary arterial hypertension (PAH): as monotherapy or in combination with endothelin receptor antagonists, for the treatment of adult patients with PAH with World Health Organisation Functional Class (WHO FC) II to III to improve exercise capacity. Efficacy has been shown in a PAH population including aetiologies or idiopathic or heritable PAH or PAH associated with connective tissue disease. **SMC restriction**: for use as a PAH-specific monotherapy as an	**Category 1** **This will be initiated by a tertiary centre and continued in Forth Valley**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	alternative treatment option to endothelin receptor antagonist (ERA) monotherapy in adult patients with PAH of WHO FC II TO III. Ot is restricted to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or by similar specialists	
Rivaroxaban 2.5mg film-coated tablets (Xarelto®) SMC No 1062/15 **Not recommended**	**Not recommended** **Indication under review:** rivaroxaban co-administered with aspirin alone or with aspirin plus clopidogrel or toclopidine, is indicated for the prevention of atherothrombotic events in adult patients after acute coronary syndrome (ACS) with elevated cardiac biomarkers.	**Not recommended by SMC therefore not included in the formulary**
Sitagliptin 25mg, 50mg and 100mg film-coated tablets (Januvia®) SMC No 1083/15	**Accepted for use.** **Indication under review:** the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.	**Category 1**
Sorafenib 200mg film-coated tablets (Nexavar®) SMC No 1055/15	**Accepted for use** **Indication under review:** treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.	**Category 2**
Tafluprost 15micrograms/mL and timolol 5mg/mL preservative-free eye drops (Taptiqom®) SMC No 1085	**Accepted for restricted use.** **Indication under review:** Reduction of intraocular pressure in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative-free eye drops. **SMC restriction:** to use in patients who have proven sensitivity to preservatives.	**Category 4**
Tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®) SMC No 1080/15	**Accepted for restricted use** **Indication under review:** the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults: • Use in patients with ABSSSI caused by Gram-positive *Staphylococcus aureus* (specifically methicillin-resistant *Staphylococcus aureus* [MRSA] isolates) • Use of tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacterial on the specific advice of local microbiologists or specialists in infectious disease.	**Category 4**
Tigecycline 50mg powder for solution for infusion (Tygacil®)	Not recommended. **Indication under review:** Treatment in children from the age of eight years for the following infections: • complicated skin and soft tissue infections, excluding diabetic foot infections • complicated intra-abdominal infections	**Not recommended by SMC therefore not included in the formulary**
Tinzaparin 20,000 IU/ml 0.4ml, 0.5ml, 0.6ml, 0.7ml, 0.8ml and 0.9ml pre-filled syringe (Innohep Syringe®) SMC No 1061/15	**Accepted for use** **Indication under review:** patients with solid tumours: extended treatment of symptomatic venous thrombo-embolism (VTE) and prevention of its recurrence.	**Category 4**
Titropium, 2.5 micrograms, solution for inhalation (Spiriva®Respimat®) SMC No 1028/15	**Accepted for use** **Indication under review:** as add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta$_2$ agonists and who experienced one or more severe exacerbations in the previous year.	**Category 2** **The annual respiratory review is due and this will be taken into consideration at this review.**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin®) SMC No 623/10 **Resubmission**	**Accepted for restricted use** **Indication under review:** in combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. It is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay. **SMC restriction:** for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser").	**Category 1**
Travoprost 40 micrograms/mL eye drops (Travatan®) SMC No 1091/15 **Product Update**	**Accepted for use** **Indication under review:** decrease of elevated intraocular pressure in paediatric patients aged 2 months to <18 years with ocular hypertension or paediatric glaucoma.	**Category 1**
Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) SMC No 1064/15	**Accepted for restricted use** **Indication under review:** for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. **SMC restriction:** for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNFα antagonist.	**Category 6**
Vinflunine (as ditartrate), 25mg/mL, concentrate for solution for infusion (Javlor®) SMC No 686/11 **Resubmission**	**Not recommended** **Indication under review:** monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen. Efficacy and safety of vinflunine have not been studied in patients with performance status ≥2.	**Not recommended by SMC therefore not included in the formulary**

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Infliximab 100mg powder for concentrate for solution for infusion (Remsima®) SMC No 1006/4	**Accepted for restricted use** **Indication under review**: rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function in: • adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; • adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. Infliximab (Remsima®) is also indicated in the following conditions: adult and paediatric, Crohn's disease and ulcerative colitis; adult psoriatic arthritis, psoriasis and ankylosing spondylitis. **SMC restriction**: Infliximab (Remsima®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab (Remicade®)	Category 2 2/4/15	Category 1

Infliximab 100mg powder for concentrate for solution for infusion (Infectra®) SMC No 1007/14	**Accepted for restricted use** **Indication under review**: rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function in: • adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; • adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs Infliximab (Inflectra®) is also indicated in the following conditions: adult and paediatric Crohn's disease and ulcerative colitis; adult ankylosing spondylitis, psoriatic arthritis and psoriasis. **SMC restriction**: Infliximab (Inflectra®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®]	Category 2 2/4/15	Category 4
Aclidinium formoterol fumarate dehydrate 340/12 micrograms inhalation powder (Duaklir Genuair®) SMC No 1034/15	**Accepted for use** **Indication under review**: maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive-pulmonary disease.	Category 2 2/4/15	Category 4
Sucroferric oxyhydroxide 500mg chewable tablets (Velphoro®) SMC No 1035/15	**Accepted for use** **Indication under review**: for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD). It should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy vitamin D3 or one of its analogues, or calcimimetics to control the development of renal bone disease.	Category 6 2/4/15	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