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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 335 – Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/335**	**Not been reviewed by SMC yet** **Indication**: for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elated cardiac biomarkers.	**Advice due 13/7/15**	**Yes**
NICE technology appraisal guidance 336 – Empagliflozin in combination therapy for treating type 2 diabetes	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/336**	**Accepted for restricted use** **Indication under review**: 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. **SMC restriction:** to use in the following situations: • Dual therapy in combination with metformin, when sulphonylurea is inappropriate • Triple therapy in combination with metformin plus standard of care • Add-on to insulin therapy in combination with insulin plus standard of care	**13/10/14**	**Yes**
NICE technology appraisal guidance 337 - rifaximin for preventing episodes of overt hepatic encephalopathy	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/337**	**Accepted for use** **Indication under review**: reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥ 18 years of age.	**9/9/13**	**Yes**
NICE technology appraisal guidance 338 – Pomalidomide for relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/338**	**Accepted for use** **Indication under review**: in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.		**No**

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®)	**Not recommended** **Indication under review:** 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.	**Not recommended by SMC therefore not included in the formulary**
Aclidinium/formoterol fumarate dehydrate 340/12 micrograms inhalation powder (Duaklir Genuair®)	**Accepted for use** **Indication under review:** maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	**Category 2**
Adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®) SMC No 1050/15 **PRODUCT UPDATE**	**Accepted for restricted use** **Indication under review:** for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology).	**Category 6**
Apixaban, 2.5mg & 5mg, film-coated tablets (Eliquis®)	**Accepted for use** **Indication under review:** treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults.	**Category 1** **For use within SMC guidance**
Apremilast 10mg, 20mg and 30mg film-coated tablets (Otezla®) SMC No 1052/15	**Accepted for restricted use** **Indication under review:** for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). **SMC restriction:** for use in patients with: • Severe psoriasis (PASI≥10 AND DLQI>10) before the use of biologic therapies. • Moderate psoriasis (PASI> and DLQI≤10) who are ineligible for biologic therapy and would otherwise receive best supportive care.	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Apremilast 10mg, 20mg, 30mg tablets (Otezla®) SMC No 1053/15	**Accepted for restricted use** **Indication under review:** alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. **SMC restriction:** for use in adult patients with active PsA who have had an inadequate response with at least two prior DMARD therapies or who are intolerant to such therapies.	**Category 6**
Budesonide, 3mg, gastro-resistant capsules (Budenofalk®) SMC No 1043/15	**Accepted for restricted use** **Indication under review:** autoimmune hepatitis. **SMC restriction:** for use in non-cirrhotic patients who are intolerant of conventional oral corticosteroids (prednisolone) with severe corticosteroid-related side effects (actual or anticipated) such as psychosis, poorly controlled diabetes or osteoporosis.	**Category 6**
Cabozantinib 20mg and 80mg hard capsules (Cometriq®)	**Not recommended** **Indication under review:** for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma.	**Not recommended by SMC therefore not included in the formulary**
Cangrelor (Kengraxel®)	Not recommended Indication under review: co-administered with acetylsalicylic acid for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention who have not received an oral P2Y12 inhibitor is not feasible or desirable.	**Not recommended by SMC therefore not included in the formulary**
Collagenase clostridium histolyticum (Xiapex®) SMC No 1059/15	**Not recommended** **Indication under review:** treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.	**Not recommended by SMC therefore not included in the formulary**
Dabrafenib, 50mg and 75mg hard capsules (Tafinlar®)	**Accepted for restricted use** **Indication under review:** monotherapy treatment of adult patients with unresectable or metastatic melanoma with BRAF V600 mutation. **SMC restriction**: for use in patients with unresectable or metastatic BRAFV600 mutation-positive metastatic melanoma who have received no prior therapy.	**Category 2**
Dexamethasone 700 micrograms intravitreal implant in applicator (Ozurdex®) SMC No 1046/15	**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.	**Category 1**
Entecavir 0.5 and 1mg film-coated tablets and 0.05mg/mL oral solution (Baraclude®) SMC No 1049/15 **PRODUCT UPDATE**	**Accepted for restricted use** **Indication under review:** treatment of chronic hepatitis B virus infection in nucleoside naïve paediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum alanine aminotransferase levels, or histological evidence of moderate to severe inflammation and/or fibrosis. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric infectious disease.	**Category 1**
Fingolimod 0.5mg hard capsules (Gilenya®)	**Accepted for use** **Indication under review:** as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: - patients with high disease activity despite treatment with at least one disease modifying therapy.	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt®) **PRODUCT UPDATE**	**Accepted for restricted use** **Indication under review:** for the treatment of the following infections in adults and children including neonates: - Acute osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.	**Category 4**
Idelalisib 100mg and 150mg tablets (Zydelig®)	**Accepted for restricted use** **Indication under review:** in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • Who have received at least one prior therapy, or • As first line treatment in the presence of 17p deletion of TP53 mutation in patients unsuitable for chemo-immunotherapy. **SMC restriction**: patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	**Category 6**
Idelalisib 100mg and 150mg tablets (Zydelig®) SMC No 1039/15	**Accepted for use** **Indication under review:** monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.	**Category 2**
Infliximab, 100mg, powder for concentrate for solution for infusion (Remsima®)	**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**
Infliximab, 100mg, powder for concentrate for solution for infusion (Inflectra®)	**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 psoriatic arthritis, psoriasis and ankylosing spondylitis. 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**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Insulin Degludec (Tresiba®) SMC No 1060/15	**Not recommended** **Indication under review:** treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year.	**Not recommended by SMC therefore not included in the formulary**
Ledipasvir/sofosbuvir, 90mg/400mg, film-coated tablet (Harvoni®)	**Accepted for restricted use** **Indication under review:** treatment of chronic hepatitis C (CHC) in adults. **SMC restriction**: genotype 1 and 4 CHC only.	**Category 1**
Levonorgestrel 20 micrograms/24 hours intrauterine delivery system (Levosert®) SMC No 1058/15 **PRODUCT UPDATE**	**Accepted for use** **Indication under review**: contraception, heavy menstrual bleeding.	**Category 5**
Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®)	**Accepted for use** **Indication under review:** contraceptive for up to 3 years.	**Category 6**
Linagliptin 5mg tablet (Trajenta®) SMC No 850/13 **RESUBMISSION**	**Accepted for use** **Indication under review:** the treatment of type 2 diabetes mellitus to improve glycaemic control in adults in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	**Category 1**
Linagliptin2.5mg plus metformin 850mg and linagliptin 2.5mg plus metformin 1000mg film-coated tablets (Jentadueto®) SMC No 1057/15 **PRODUCT UPDATE**	**Accepted for restricted use** **Indication under review**: for the treatment of adult patients with type 2 diabetes mellitus in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide adequate glycaemic control. **SMC restriction**: to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and the fixed doses are considered appropriate.	**Category 1**
Liraglutide 6mg/mL prefilled pen for injection (3mL) (Victoza®) SMC No 1044/15	**Accepted for use** **Indication under review:** for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with basal insulin when this, together with diet and exercise, does not provide adequate glycaemic control.	**Category 1**
Nintedanib 100mg and 150mg soft capsules (Vargatef®)	**Accepted for use** **Indication under review:** in combination with docetaxel for the treatment of adult patients locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSSLC) of adenocarcinoma tumour histology after first-line chemotherapy.	**Category 6**
Ofatumumab 100mg and 1,000mg concentrate for solution for infusion (Arzerra®) SMC No 1037/15	**Accepted for restricted use** **Indication under review:** ofatumumab in combination with chlorambucil or bendamustine is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior therapy and who are not eligible for fludarabine-based therapy. **SMC restriction**: for use in patients who would not be considered for bendamustine therapy and who would receive chlorambucil-based therapy.	**Category 2**
Ombitasvir 12.5mg/ paritaprevir75mg/ ritonavir 50mg (Viekirax®) film-coated tablet and dasabuvir 250 (Exviera®) film-coated tablet SMC No 1051/15	**Accepted for use** **Indication under review:** • Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with dasabuvir (Exviera®) with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults • Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with ribavirin for the treatment of genotype 4 CHC in adults	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Paclitaxel albumin (Abraxane®) SMC No 1071/15	**Not recommended** **Indication under review**: in combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.	**Not recommended by SMC therefore not included in the formulary**
Ponatinib 15mg, 45mg film-coated tablets (Iclusig®)	**Accepted for use** **Indication under review:** adult patients with • Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T3151 mutation. • Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T3151 mutation.	**Category 2**
Regorafenib 40mg film-coated tablet (Stivarga®)	**Accepted for use** **Indication under review:** treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.	**Category 6**
Ruxolitinib (as phosphate), 5mg, 15mg, & 20mg tablets (Jakavi®)	**Accepted for use** **Indication under review:** the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	**Category 2**
Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) SMC No 1054/15	**Accepted for restricted use** **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.	**Category 1**
Sucroferric oxyhydroxide 500mg chewable tablets (Velphoro®)	**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**
Tacrolimus (as monohydrate) 0.75mg, 1mg and 4mg prolonged-release tablets (Envarsus®)	**Accepted for use** **Indication under review:** prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.	**Category 1**
Vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) SMC No 1045/15	**Accepted for use** **Indication under review:** the treatment of adult patients with moderately to severely active ulcerative colitis 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.	**Category 6**

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Brentuximab vedotin 50mg powder for concentrate for solution (Adcetris®) SMC No 989/14	**Indication under review:** treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). **SMC restriction:** treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option	Category 6 25/9/15	Category 1
Pemetrexed, 100mg & 500mg powder for concentrate for solution for infusion (Alimta®) SMC No 770/12	**Indication under review:** monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.	Category 2 20/11/14	Category 1
Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) SMC No 997/14	**Indication under review:** Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use).	Category 2 20/11/14	Category 1
Obinutuzumab, 1000mg concentrate for solution for infusion (Gazyvaro®) SMC No 1008/14	**Indication under review:** In combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy.	Category 6 20/11/14	Category 1
Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) SMC No 595/10	**Indication under review:** the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.	Category 2 20/11/14	Category 1
Pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) SMC No 972/14	**Indication under review:** in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.	Category 2 20/11/14	Category 1
Cetuximab 100mg/20ml and 500mg/100ml solution for infusion (Erbitux®) SMC No 1012/14	**Indication under review:** Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer: • in combination with irinotecan-based chemotherapy • in first-line in combination with FOLFOX; • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. **SMC restriction:** 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).	Category 6 22/1/15	Category 1

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Aztreonam lysine, 75mg, powder and solvent for nebuliser solution (Cayston®) SMC No 753/12	**Indication under review:** Suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged six years and older. **SMC restriction:** When inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit (measured as ≥2% decline in forced expiratory volume in 1 second [FEV_1]).	Category 6 22/1/15	Category 5
Bosutinib 100mg, 500mg film-coated tablets (Bosulif®) SMC No 910/13	**Indication under review:** 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.	Category 6 22/1/15	Category 1
Pacitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®) SMC No 968/14	**Indication under review:** in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	Category 6 22/1/15	Category 1
Ruxolitinib (as phosphate), 5mg, 15mg & 20mg tablets (Jakavi®) SMC No 867/13	**Indication under review:** the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	Category 2 2/4/15	Category 1
Infliximab, 100mg powder for concentrate for solution (Remsima®) SMC No 1006/14	**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.[1] **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 2 (This will remain as a category 2 until there has been agreement by National Procurement

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Infliximab, 100mg powder for concentrate for solution (Inflectra®) SMC No 1007/14	**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.[1] **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 2 (This will remain as a category 2 until there has been agreement by National Procurement
Darefenib, 50mg and 75mg hard capsules (Tafinlar®) SMC No 1023/15	**Indication under review:** monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. **SMC restriction:** for use in patients with unresectable or metastatic BRAFV600 mutation-positive metastatic melanoma who have received no prior therapy.	Category 2 2/4/15	Category 1
Idelalisib 100mg and 150mg tablets (Zydelig®) SMC No 1026/15	**Indication under review:** In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • who have received at least one prior therapy, or • as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. **SMC restriction:** patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	Category 6 2/4/15	Category 1
Nintedanib 100mg and 150mg soft capsules (Vargatef®) SMC No 1027/15	**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.	Category 6 2/4/15	Category 1
Regorafenib 40mg film-coated tablets (Stivarga®) SMC No 1031/15	**Indication under review:** Treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.	Category 6 2/4/15	Category 1

Drug (approved by SMC)	SMC Advice	Previous decision and date	New FV Formulary position
Ponatinib 15mg, 45mg film coated tablets (Iclusig®) SMC No 1032/15	**Indication under review:** Adult patients with • Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. • Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.	Category 2 2/4/15	Category 1
Alclidinium formoterol fumarate dehydrate 340/12 micrograms inhalation powder (Duaklir Genuair®) SMC No 1034/15	**Indication under review:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	Category 2 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