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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 No 386 Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/386**	**Accepted for use** **Indication under review**: 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	**9/3/15**	Yes
NICE technology appraisal guidance No 387 Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/387**	**Accepted for use** **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.	**12/10/15**	Yes
NICE technology appraisal guidance No 388 Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/388**	**Accepted for use** **Indication under review:** in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.	**7/3/16**	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
NICE technology appraisal guidance No 389 Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/398**	**Topotecan** **Accepted for restricted use** **Indication under review:** in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with stage IVB disease. It is restricted to patients who are cisplatin-naïve. **Trabectedin** **Not recommended** **Indication under review:** in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.	**10/12/07** **13/9/10**	All on formulary

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**

Category Table B (New Guidance from March 2016)

Drugs Approved / Not Recommended By SMC

Category 1	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
Category 2	Available in line with local guidance for prescribing
Category 3	Available from a specialist centre in another NHS Board
Category 4	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Category 5	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance if appropriate)
Category 6	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – date decision expected to be included

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
Adalimumab 40mg/0.8mL solution for injection (Humira®) SMC No 1143/16 http://www.scottishmedicines.org.uk/files/advice/adalimumab__Humira__FINAL_April_2016_for_website.pdf	**Accepted for use** **Indication under review:** treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Alendronic acid 70mg effervescent tablet (Binosto®) SMC No 1137/16 **Product Update** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1137_16_alendronic_acid_Binosto/alendronic_acid_Binosto_ABBREVIATED	**Accepted for restricted use** **Indication under review:** Treatment of postmenopausal osteoporosis. **SMC restriction:** for use in patients who are unable to swallow tablets where alendronic acid is the appropriate treatment choice.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ataluren 125mg, 250mg, 1,000mg granules for oral suspension (Translarna®) SMC No 1131/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1131_16_ataluren_Translarna/ataluren_Translarna	**Not recommended** **Indication under review:** Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) SMC No 1135/16 http://www.scottishmedicines.org.uk/files/advice/bevacizumab__Avastin__FINAL_April_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. **Restriction**: for use in combination with cisplatin and paclitaxel.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Blinatumomab, 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®) SMC No 1145/16 http://www.scottishmedicines.org.uk/files/advice/DAD_blinatumomab_Blincyto_FINAL_May_2016_for_website.pdf	**Accepted for use** **Indication under review:** the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL).	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®) SMC No 735/11 http://www.scottishmedicines.org.uk/files/advice/DAD_cabazitaxel_Jevtana_Resubmission_FINAL_May_2016_for_website.pdf	**Not recommended** **Indication under review:** cabazitaxel, in combination with prednisone or prednisolone, is indicated for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Camellia sinensis (green tea) leaf extract 10% ointment (Catephen®) SMC No 1133/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1133_16_camellia_sinensis_green_tea_leaf_Catephen/camellia_sinensis_green_tea_leaf_Catephen	**Accepted for restricted use** **Indication under review:** Cutaneous treatment of external genital and perianal warts (*condylomata acuminata*) in immunocompetent patients from the age of 18 years. **SMC restriction:** for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Ceftolozane/tazobactam 1g/0.5g powder for concentrate for solution for infusion (Zerbaxa®) SMC No 1146/16 http://www.scottishmedicines.org.uk/files/advice/ceftolozane-tazobactam__Zerbaxa__FINAL_April_2016_for_website.pdf	**Not recommended** **Indication under review:** for the treatment of the following infections in adults: - Complicated intra-abdominal infections - Acute pyelonephritis - Complicated urinary tract infections	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Certolizumab pegol (Cimzia®) 200 mg solution for injection SMC 1155/16 http://www.scottishmedicines.org.uk/files/advice/certolizumab_pegol__Cimzia__Non_Sub_FINAL_April_2016_for_website.pdf	**Not recommended** **Indication under review:** Treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®) SMC No 316/06 **Resubmission** http://www.scottishmedicines.org.uk/files/advice/DAD_cocareldopa_2nd_Resubmission_FINAL_May_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. **SMC restriction:** for use in patients not eligible for deep brain stimulation.	**Category 1** Available in line with national guidance
Eculizumab 300mg/30mL vial concentrate for solution for infusion (Soliris®) SMC No 1130/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1130_16_eculizumab_Soliris_PNH/eculizumab_Soliris_for_PNH	**Not recommended** **Indication under review:** In adults and children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Eltrombopag olamine (Revolade®) 25 mg / 50 mg film-coated tablets SMC No 1164/16 http://www.scottishmedicines.org.uk/files/advice/DAD_eltrombopag_olamine_Revolade_Non-Sub_FINAL_May_2016_for_website.pdf	**Not recommended** **Indication under review:** treatment in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Genvoya®) SMC No 1142/16 http://www.scottishmedicines.org.uk/files/advice/elvitegravir__Genvoya__FINAL_April_2016_for_website.pdf	**Accepted for use** **Indication under review:** the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) SMC No 872/13 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/872_13_everolimus_Afinitor/everolimus_Afinitor_2nd_RESUBMISSION	**Accepted for use** **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.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Evolocumab, 140mg, solution for injection in pre-filled pen (Repatha® Sureclick) or pre-filled syringe (Repatha® PFS) SMC No 1148/16 http://www.scottishmedicines.org.uk/files/advice/DAD_evolocumab_Repatha_FINAL_May_2016_for_website.pdf	**Not recommended** • **Indication under review:** In adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or, • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. • In adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Febuxostat 120mg film-coated tablet (Adenuric®) SMC No 1153/16 http://www.scottishmedicines.org.uk/files/advice/DAD_febuxostat_Adenuric_FINAL_May_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS). **SMC restriction:** prevention of hyperuricaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated, such as: • Those intolerant of allopurinol • Those in whom allopurinol is contraindicated, e.g. patients with renal impairment	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Isavuconazole, 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®) SMC No 1129/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1129_16_isavuconazole_Cresemba/isavuconazole_Cresemba	**Accepted for use** **Indication under review:** in adults for the treatment of: • invasive aspergillosis • mucormycosis in patients for whom amphotericin B is inappropriate	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Ivacaftor 50mg and 75mg granules in sachet (Kalydeco®) SMC No 1134/16 http://www.scottishmedicines.org.uk/files/advice/ivacaftor_granules_Kalydeco_FINAL_April_2016_for_website.pdf	**Not recommended** **Indication under review:** treatment of children with cystic fibrosis (CF) aged 2 years and older and weighing less than 25kg who have one of the following gating (class III) mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N* or *S549R.*	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Lumacaftor 200mg, ivacaftor 125mg film-coated tablet (Orkambi®) SMC No 1136/16 http://www.scottishmedicines.org.uk/files/advice/lumacaftor-ivacaftor_Orkambi_FINAL_April_2016_for_website.pdf	**Not recommended** **Indication under review:** treatment of cystic fibrosis (CF) in patients aged 12 years and older who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Naproxen 250mg effervescent tablets (Stirlescent®) SMC No 1154/16 http://www.scottishmedicines.org.uk/files/advice/DAD_for_Abb_naproxen_effervescent_tablets_FINAL_May_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults. **SMC restriction:** use in patients unable to swallow naproxen tablets.	**Category 1** Available in line with national guidance
Mepolizumab 100mg powder for solution for injection (Nucala®) SMC No 1149/16 http://www.scottishmedicines.org.uk/files/advice/DAD_mepolizumab_oesinophilic_asthma_FINAL_May_2016_Amended_08.06.16_10.06.16_for_website.pdf	**Accepted for restricted use** **Indication under review:** as an add-on treatment for severe refractory eosinophilic asthma in adult patients. **SMC restriction:** patients who have eosinophils of at least 150 cells per microlitre (0.15×10^9/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No 1120/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1120_16_nivolumab_Opdivo/nivolumab_Opdivo	**Not recommended** **Indication under review:** as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Ramucirumab (Cyrmaza®) 10 mg/ml concentrate for solution for infusion SMC 1156/16 http://www.scottishmedicines.org.uk/files/advice/ramucirumab__Cyrmaza__Non_Sub_FINAL_April_2016_for_website.pdf	**Not recommended** **Indication under review:** in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) for the treatment of adult patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Ramucirumab (Cyrmaza®) 10 mg/ml concentrate for solution for infusion SMC 1165/16 http://www.scottishmedicines.org.uk/files/advice/DAD_ramucirumab_Cyramza_Non-_Sub__FINAL_May_2016_for_website.pdf	**Not recommended** **Indication under review:** in combination with docetaxel for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Ruxolitinib phosphate (Jakavi®) 5mg, 10mg, 15mg and 20mg tablets 1166/16 http://www.scottishmedicines.org.uk/files/advice/DAD_ruxolitinib_Jakavi_Non-Sub_FINAL_May_2016_for_website.pdf	**Not recommended** **Indication under review:** treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Titropium, 2.5 micrograms, solution for inhalation (Spiriva® Respimat®) SMC No 1028/15 http://www.scottishmedicines.org.uk/files/advice/tiotropium_Spiriva_FINAL_July_2015_for_website.pdf	**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 beta2 agonists and who experienced one or more severe exacerbations in the previous year.	Category 5 – not included because clinicians do not support the formulary inclusion *(this was from the old category classification indicated in the table below)*	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16. *The respiratory asthma review will be undertaken soon and place in therapy will be discussed at this meeting.*
Gefitinib 250mg film-coated tablets (Iressa®) SMC No 615/10 http://www.scottishmedicines.org.uk/files/advice/gefitinib__Iressa__2nd_Resub_FINAL_Nov_2015_for_website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).	Category 6 Not included pending protocol *(this was from the old category classification indicated in the table below)* 3/12/16	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16.
Nitedanib 100mg and 150mg capsules (Ofev®) SMC No 1076/15 http://www.scottishmedicines.org.uk/files/advice/nintedanib__Ofev__FINAL_September_2015_Amended_06.10.15_for_website.pdf	**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 6 Not included pending protocol *(this was from the old category classification indicated in the table below)* 3/12/16	**Category 1** Available in line with national guidance
Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®) SMC No 1096/15 http://www.scottishmedicines.org.uk/files/advice/lenalidomide__Revlimid__FINAL_Nov_2015_Amended_27.11.15_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. **SMC restriction**: for use in patients unsuitable for thalidomide-containing regimens	Category 2 Included pending protocol *(this was from the old category classification indicated in the table below)* 3/12/16	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Ceritinib 150mg hard capsules (Zykadia®) SMC No 1097/15 http://www.scottishmedicines.org.uk/files/advice/ceritinib__Zykadia__FINAL_Nov_2015_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.	Category 6 Not included pending protocol *(this was from the old category classification indicated in the table below)* 3/12/16	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16.
Naloxegol 12mg and 25mg film-coated tablets (Moventig®) SMC No 1106/15 http://www.scottishmedicines.org.uk/files/advice/naloxegol__Moventig__FINAL_Nov_2015_for_website.pdf	**Accepted for use** **Indication under review:** the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s).	Category 6 Not included pending protocol *(this was from the old category classification indicated in the table below)* 3/12/16	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16.
Eribulin (mesilate), 0.44mg/mL solution for injection (Halaven®) SMC No 1065/15 http://www.scottishmedicines.org.uk/files/advice/eribulin_Halaven_Resubmission_FINAL_February_2016_for_website.pdf	**Accepted for restricted use** **Indication under review**: for the treatment of adult 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. **SMC restriction**: for use in patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice meeting 10/3/16	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16
Enzalutamide 40mg soft capsules (Xtandi®) SMC No 1066/15 http://www.scottishmedicines.org.uk/files/advice/enzalutamide_Xtandi_IRP_FINAL_Feb_2016_for_website.pdf	**Accepted for use** **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.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice meeting 10/3/16	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice – decision expected by 28/7/16.

Decisions Categories Table up until March 2016 (after that date a new category table has been used as indicated at the beginning of the newsletter)

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

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