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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 363 – Ledipasvir-Sofosbuvir for treating Chronic Hepatitis C	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/363**	**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.	**7/9/15**	Yes
NICE technology appraisal guidance No 364 – Daclatasvir for treating Hepatitis C	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/364**	**Accepted for restricted use** **Indication under review**: in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction**: use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis.	**10/11/14**	Yes
NICE technology appraisal guidance No 365 – Ombitasvir-Paritaprevir-Ritonavir with or without Dasabuvir for treating Hepatitis C	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/365**	**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.	**8/6/15**	Yes
NICE technology appraisal guidance No 366 – Pembrolizumab for advanced melanoma not previously treated with Ipilimumab	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/366**	**Accepted for use** **Indication under review**: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.	**9/11/15**	No
NICE technology appraisal guidance No 367 – Vortioxetine for treating major depressive episodes	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/367**	**Not been through the SMC process yet, in Forthcoming submissions**	**Not been through SMC yet – forthcoming submission**	No

NICE technology appraisal guidance No 368 – Apremilast for treating moderate to severe Plaque Psoriasis	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/368**	**Accepted for 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)	**8/6/15**	Yes
NICE technology appraisal guidance No 369 – Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/369**	**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.	**12/10/15**	Yes
NICE technology appraisal guidance No 370 Bortezomib for previously untreated mantle cell lymphoma	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/370**	**Accepted for use** **Indication under review**: in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.	**7/9/15**	Yes
NICE technology appraisal guidance No 371 Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and taxane	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/371**	**Not recommended** **Indication under review**: as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should either have: - received prior therapy for locally advanced or metastatic disease, or - developed disease recurrence during or within six months of completing adjuvant therapy.	**13/10/14**	Yes
NICE technology appraisal guidance No 372 Apremelist for treating active psoriatic arthritis	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/372**	**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.	**8/6/15**	Yes

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 373 Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/373**	**Abatacept** **Accepted for restricted use** **Indication under review**: in combination with methotrexate, abatacept is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients aged 6 years and older who have had an insufficient response to other disease modifying antirheumatic drugs (DMARDS) including at least one tumour necrosis factor (TNF) inhibitor. It has not been studied in children under 6 years old. **Adalimumab** **Accepted for restricted use** **Indication under review**: in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 2 years. SMC restriction: use within specialist rheumatology services (including those	**7/11/11** **8/7/13**	All on formulary

		working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations. **Etanercept** **Accepted for restricted use** **Indication under review**: for the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerance of, methotrexate. SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology). **Tocilizumab** **Accepted for use** **Indication under review**: tocilizumab in combination with methotrexate is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with methotrexate. Tocilizumab can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate.	**14/5/12** **13/1/14**	
NICE technology appraisal guidance No 374 Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/374**	**Erlotinib** **Accepted for use** **Indication under review**: first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations. **Gefitinib** **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). SMC restriction: in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as first-line therapy.	**16/1/12** **7/12/15**	Erlotinib – Yes Gefitinib – No

All information provided by this newsletter constitutes the most current advice of the Forth Valley Area Drug and Therapeutics Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in future.
For full SMC advice on specific drugs please refer to the SMC website **www.scottishmedicines.org**

In March 2016 the ADTC Collaborative working with Healthcare Improvement Scotland (HIS) developed new categories for classifying new medicines to be used by all NHS Scotland Health Boards to ensure consistency across all Board areas.
These new categories in Table B have been used for classifying some on the medications that were reviewed after the guidance was issued.

Category Table A

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

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
Albiglutide 30mg and 50mg pre-filled pen (Eperzan®) SMC No 1024/15 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1024_15_albiglutide_Eperzan/albiglutide_Eperzan	**Accepted for restricted use** **Indication under review:** Treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** an alternative once weekly glucagon-like peptide-1 (GLP-1) agonist for use in combination with oral anti-diabetic agents as a third-line pre-insulin treatment option.	**Category 6 (classification from table A)**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Capsaicin (Qutenza®) 179mg cutaneous patch **SMC No 1140/16** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1140_16_capsaicin_Qutenza/capsaicin_Quetenza_Non_Submission	**Not recommended** **Indication under review:** Treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain.	**Not recommended by SMC therefore not included in the formulary for this indication**
Daptomycin (Cubicin®) powder for concentrate for solution for injection or infusion **SMC No 1141/16** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1141_16_daptomycin_Cubicin/daptomycin_Cubicin_Non_Submission	**Not recommended** **Indication under review:** Treatment of paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections.	**Not recommended by SMC therefore not included in the formulary for this indication**
Dulaglutide 0.75mg and 1.5mg solution for injection in pre-filled pen (Trulicity®) **SMC No 1110/15** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1110_15_dulaglutide_Trulicity/dulaglutide_Trulicity	**Accepted for restricted use** **Indication under review:** in adults with type 2 diabetes mellitus to improve glycaemic control as add-on 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:** as part of a triple therapy in patients with inadequate glycaemic control on two oral anti-diabetic drugs, as an alternative glucagon-like peptide 1 (GLP-1) agonist option.	**Category 6 (classification from table A)**
Eculizumab 300mg concentrate for solution for infusion (Soliris®) **SMC No 767/12** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/767_12_eculizumab_Soliris/eculizumab_Soliris_aHUS	**Not recommended** **Indication under review:** in adults and children for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS).	**Not recommended by SMC therefore not included in the formulary for this indication**
Enzalutamide 40mg soft capsules (Xtandi®) SMC No 1066/15 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1066_15_enzalutamide_Xtandi/enzalutamide_Xtandi_IRP	**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 (classification from table B) – decision expected by 26/5/16**
Eribulin (mesilate), 0.44mg/mL solution for injection (Halaven®) **SMC No 1065/15** **Resubmission** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1065_15_eribulin_Halaven/eribulin_Halaven_Resubmission	**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 (classification from table B) – decision expected by 26/5/16**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Fulvestrant, 250mg, solution for injection (Faslodex®) SMC No 114/04 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/114_04_fulvestrant_Faslodex/fulvestrant_Faslodex_Resubmission	**Accepted for use** **Indication under review:** for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.	**Category 6 (classification from table A)**
Golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®) SMC No 1124/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1124_16_golimumab_Simponi/golimumab_Simponi	**Accepted for use** **Indication under review:** treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).	**Category 1 (classification from table A)**
Guanfacine, 1mg, 2mg, 3mg and 4mg prolonged-release tablets (Intuniv®) SMC No 1123/16 http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1123_16_guanfacine_hydrochloride_Intuniv/guanfacine_hydrochloride_Intuniv	**Accepted for use** **Indication under review:** treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.	**Category 2 (classification from table A)**
Insulin detemir 100units/mL, solution for injection in cartridge (Penfill), pre-filled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®) SMC No 1126/16 **Product Update** http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1126_16_insulin_detemir_Levemir/insulin_detemir_Levemir_Abbreviated	**Accepted for restricted use** **Indication under review**: for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. **SMC restriction**: in patients unable to achieve good glycaemic control with established insulins.	**Category 1 (classification from table B)**
Netupitant/palonosetron 300mg/0.5mg, hard capsule (Akynzeo®) SMC No 1109/15 http://www.scottishmedicines.org.uk/files/advice/netupitant_palonostron_Akynzeo_FINAL_Dec_2015_for_website.pdf	**Accepted for restricted use** **Indication under review:** in adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy. **SMC restriction:** prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.	**Category 6 (classification from table A)**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No 1120/16 http://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_FINAL_February_2016_Amended_16.02.16_for_website.pdf	**Not recommended** **Indication under review**: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults.	**Not recommended by SMC therefore not included in the formulary for this indication**
0seltamivir 30mg, 45mg, 75mg capsules and 6mg/mL powder for oral suspension (Tamiflu®) SMC No 1127/16 Product Update http://www.scottishmedicines.org.uk/files/advice/oseltamivir_Tamiflu_Abbreviated_FINAL_Feb_2016_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.	**Category 1 (classification from table B)**
Panobinostat, 10mg, 15mg and 20mg hard capsules (Farydak®) SMC No 1122/16 http://www.scottishmedicines.org.uk/files/advice/panobinostat_Farydak_FINAL_January_2016_amended_030216_for_website.pdf	**Accepted for use** **Indication under review:** In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent.	**Category 6 (classification from table A)**
Pixantrone (Pixuvri®) 29 mg powder for concentrate for solution for infusion SMC No 1138/16 http://www.scottishmedicines.org.uk/files/advice/pixantrone_Pixuvri_Non_Sub_FINAL_Jan_2016_for_website.pdf	**Not recommended** **Indication under review:** As monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non Hodgkin B-cell Lymphomas.	**Not recommended by SMC therefore not included in the formulary for this indication**
Pertuzumab 420mg concentrate for solution for infusion vial (Perjeta®) SMC No 1121/16 http://www.scottishmedicines.org.uk/files/advice/pertuzumab_Perjeta_FINAL_February_2016_for_website.pdf	**Not recommended** **Indication under review:** For use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.	**Category 6 (classification from table B) – decision expected by 26/5/16**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Sacubitril/valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets (Entresto®) **SMC No 1132/16** http://www.scottishmedicines.org.uk/files/advice/sacubitril_valsartan_Entresto_FINAL_February_2016_for_website.pdf	**Accepted for use** **Indication under review:** in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.	**Category 6 (classification from table B) – decision expected by 26/5/16**
Sorafenib 200mg film-coated tablets (Nexavar®) **SMC No 482/08** **2nd Re-submission** http://www.scottishmedicines.org.uk/files/advice/sorafenib_Nexavar_2nd_Resubmission_FINAL_Dec_2015_for_website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of hepatocellular carcinoma. **SMC restriction:** in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies.	**Category 6 (classification from table A)**
Teduglutide (Revestive®) 5mg powder and solvent for solution for injection **SMC No 1139/16** http://www.scottishmedicines.org.uk/files/advice/teduglutide_Revestive_Non_Sub_FINAL_Jan_2016_for_website.pdf	**Not recommended** **Indication under review:** For the treatment of adult patients with Short Bowel Syndrome.	**Not recommended by SMC therefore not included in the formulary for this indication**
Tolvaptan 15mg, 30mg, 45mg, 60mg and 90mg tablets (Jinarc®) **SMC No 1114/15** http://www.scottishmedicines.org.uk/files/advice/tolvaptan_Jinarc_FINAL_December_2015_for_website.pdf	**Accepted for use** **Indication under review:** to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.	**Category 6 (classification from table A)**
Ulipristal acetate, 5mg, tablet (Esmya®) **SMC No 1128/16** http://www.scottishmedicines.org.uk/files/advice/ulipristal_acetate_Esmya_FINAL_January_2016_for_website.pdf	**Accepted for use** **Indication under review:** for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	**Category 6 (classification from table A)**
Ustekinumab 45mg solution for injection and prefilled syringe (Stelara®) **SMC No 1115/15** http://www.scottishmedicines.org.uk/files/advice/ustekinumab_Stelara_Abbreviated_FINAL_December_2015_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	**Category 1 (classification from table A)**

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®) SMC No 1098/15 **Product Update** http://www.scottishmedicines.org.uk/files/advice/gefitinib__Iressa__2nd_Resub_FINAL_Nov_2015_for_website.pdf	**Accepted for use** **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir.	Category 2 – (classification from table A) meeting 3/12/15	**Category 1 (classification from table A)**
Bevacizumab 25mg/ml concentrate for solution for infusion (Avastin®) SMC No 806/12 http://www.scottishmedicines.org.uk/files/advice/bevacizumab__Avastin__2nd_Resub_FINAL__Oct_2015_for_website.pdf	**Accepted for restricted use** **Indication under review:** In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. **SMC restriction:** In patients with FIGO stage IV disease	Category 6 – (classification from table A) meeting 3/12/15	**Category 3 (classification from table B)**
Certinib 150mg hard capsule (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 – (classification from table A) meeting 3/12/15	**Category 6 (classification from table B) - decision date will be 26/5/16**
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). **SMC restriction:** in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy.	Category 6 – (classification from table A) meeting 3/12/15	**Category 6 (classification from table B) - decision date will be 26/5/16**
Ivermectin, 10mg/g cream (Soolantra®) SMC No 1104/15 http://www.scottishmedicines.org.uk/files/advice/ivermectin__Soolantra__FINAL_Nov_2015_for_website.pdf	**Accepted for restricted use** **Indication under review:** topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients. **SMC restriction:** the treatment of moderate to severe inflammatory lesions of rosacea where a topical treatment is considered appropriate.	Category 6 – (classification from table A) meeting 3/12/15	**Category 1 (classification from table B)**
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 – (classification from table A) meeting 3/12/15	**Category 6 (classification from table B) - decision date will be 26/5/16**
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 – (classification from table A) meeting 3/12/15	**Category 6 (classification from table B) - decision date will be 26/5/16**
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 – (classification from table A) meeting 3/12/15	**Category 6 (classification from table B) - decision date will be 26/5/16**

Palonosetron, 250micrograms solution for injection (Aloxi®) SMC No 1073/15 **Product Update** http://www.scottishmedicines.org.uk/files/advice/palonosetron_Aloxi_Abbreviated_FINAL_July_2015_for_website.pdf	**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 – (classification from table A) meeting 30/7/15	**Category 5 (classification from table B)**
Sorafenib 200mg film-coated tablets (Nexavar®) SMC No 1055/15 http://www.scottishmedicines.org.uk/files/advice/sorafenib_Nexavar_FINAL_June_2015_for_website.pdf	**Accepted for use** **Indication under review:** treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.	Category 2 – (classification from table A) meeting 30/7/15	**Category 1 (classification from table B)**

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