October 2016
Vol. 13 No. 5

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 398 – Lumacaftor – ivacaftor for treating cystic fibrosis homozygous for the F508del mutation	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance /398**	**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.	**9/5/16**	**No**
NICE Technology Appraisal Guidance No 399 – Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance / 399**	**Not recommended Indication under review**: Treatment of adult patients aged 65 years or older who are not eligible for haematopoietic stem cell transplantation (HSCT) with acute myeloid leukaemia (AML) with >30% marrow blasts according to the World Health Organisation (WHO) classification.	**11/7/16**	**No**
NICE Technology Appraisal Guidance No 400 – Nivolumab in combination with ipilimumab for treating advanced melanoma	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance /400**	**Accepted for restricted use Indication under review:** as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. SMC restriction: patients previously untreated with ipilimumab.	**8/8/16**	**No**
NICE Technology Appraisal Guidance No 401 – Bosutinib for previously treated chronic myeloid leukaemia	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance /401**	**Accepted for use 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.	**9/2/15**	**Yes**

NICE Technology Appraisal Guidance No 402 – Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/402**	**Accepted for use 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.	**8/12/14**	**Yes**
NICE Technology Appraisal Guidance No 403 – Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/403**	**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.	**13/6/16**	**No**
NICE Technology Appraisal Guidance No 404 – Degarelix for treating advanced hormone-dependent prostate cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/404**	**Accepted for use Indication under review:** degarelix is a gonadotropin-releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer.	**17/1/11**	**Yes**
NICE Technology Appraisal Guidance No 405 – Trifluridine-tipiracil for previously metastatic colorectal cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/405**	**Not been through SMC – Forthcoming submission**	**Not applicable**	**Not applicable**

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**

Categories

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
Aflibercept 40mg/mL solution for injection (Eylea®) SMC No 1186/16 https://www.scottishmedicines.org.uk/files/advice/afliberceptEylea_FINAL_Sept_2016_for_website.pdf	**Accepted for use** **Indication under review:** for adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV).	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Bevacizumab (Avastin®) 25mg/ml concentrate for solution for infusion SMC No 1190/16 https://www.scottishmedicines.org.uk/files/advice/bevacizumab_Avastin_Non_Sub_FINAL_August_2016_for_website.pdf	**Not recommended** **Indication under review:** In combination with erlotinib for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations.	**Category 4** Not available as not recommended for use in NHS Scotland
Calcipotriol 50 micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®) SMC No 1182/16 **Product Update** https://www.scottishmedicines.org.uk/files/advice/calcipotriol_betamethasone_Enstilar_Abb_FINAL_August_2016_for_website.pdf	**Accepted for use** **Indication under review:** topical treatment of psoriasis vulgaris in adults.	**Category 1** available in line with national guidance
Budesonide 9mg prolonged release tablet (Cortiment®) SMC No 1093/15 **Resubmission** https://www.scottishmedicines.org.uk/files/advice/budesonide_Cortiment_Resub_FINAL_Sept_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient. **SMC restriction:** for use in patients with UC who present with active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone, as an alternative to budesonide rectal formulations or off-label oral budesonide.	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Budesonide/formoterol 200 micrograms/6 Inhalation powder and 400 micrograms/12 Inhalation powder (Symbicort Turbohaler®) budesonide/formoterol 200 micrograms/6 micrograms per actuation, pressurised inhalation, suspension (Symbicort®) SMC No 1198/16	**Not recommended** **Indication under review:** Treatment of patients with chronic obstructive pulmonary disease (COPD) with forced expiratory volume in 1 second (FEV_1) 50% to 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.	**Category 4** Not available as not recommended for use in NHS Scotland
Carfilzomib 60mg powder for solution for infusion (Kyprolis®) SMC No 1171/16	**Not recommended** **Indication under review:** in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Cobimetinib (Cotellic®) 20mg film-coated tablets	**Not recommended** **Indication under review:** in combination with vemurafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.	**Category 4** Not available as not recommended for use in NHS Scotland
Dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®) SMC No 371/07 **Resubmission** https://www.scottishmedicines.org.uk/files/dasatanib__Sprycel__ALL_FINAL_April_2007_for_website.pdf	**Accepted for use** **Indication under review:** for the treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate.	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®) SMC No 1170/16 https://www.scottishmedicines.org.uk/files/advice/dasatinib_Sprycel_FINAL_August_2016_for_website.pdf	**Accepted for use** **Indication under review:** for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase.	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Fosfomycin trometamol granules for oral solution (equivalent to 3g fosfomycin) (Monuril®) SMC No 1163/16 **Product Update** https://www.scottishmedicines.org.uk/files/advice/fosfomycin_trometamol_Monuril_Abbreviated_FINAL_June_2016_for_website.pdf	**Accepted for use** **Indication under review:** • Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. • Prophylaxis in diagnostic and surgical transurethral procedures.	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Golimumab (Simponi®) 50 mg solution for injection https://www.scottishmedicines.org.uk/files/advice/golimumab_Simponi_Non_Sub_FINAL_Sept_2016_for_website.pdf	**Not recommended** **Indication under review:** In combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with methotrexate.	**Category 4** Not available as not recommended for use in NHS Scotland
Idarucizumab 2.5g/50mL solution for injection/infusion (Praxbind®) SMC No 1178/16 https://www.scottishmedicines.org.uk/files/advice/idarucizumab_Praxbind_FINAL_August_2016_for_website.pdf	**Accepted for use** **Indication under review:** idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.	**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
Iron (III) isomaltoside 1000 (contains 50mg iron per mL) (Diafer®), solution for injection SMC No 1177/16 https://www.scottishmedicines.org.uk/files/advice/iron_isomaltoside_1000_Diafer_FINAL_August_2016_for_website.pdf	**Not recommended** **Indication under review:** For the treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Lenvatinib 4mg and 10mg hard capsules (Lenvima®) SMC No 1179/16 https://www.scottishmedicines.org.uk/files/advice/lenvatinib_Lenvima_FINAL_Sept_2016_amended_30.09.16_for_website.pdf	**Accepted for use** **Indication under review:** treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Liraglutide (Victoza®) 6mg/ml solution for injection in pre-filled pen SMC No 1192/16 https://www.scottishmedicines.org.uk/files/advice/liraglutide_Victoza_Non_Sub_FINAL_August_2016_for_website.pdf	**Not recommended** **Indication under review:** As monotherapy for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance or contraindications.	**Category 4** Not available as not recommended for use in NHS Scotland
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No 1180/16 https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_FINAL_Sept_2016_FINAL_amended_150916_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. **SMC restriction:** treatment with nivolumab is subject to a two-year clinical stopping rule.	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts
Paliperidone palmitate 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection (Trevicta®) SMC No 1181/16 **Product Update** https://www.scottishmedicines.org.uk/files/advice/paliperidone_palmitate_Trevicta_Abb_FINAL_August_2016_for_website.pdf	**Accepted for use** **Indication under review:** paliperidone palmitate (Trevicta®), a three-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product.	**Category 2** available in line with local guidance for prescribing
Perampanel (Fycompa®) 2mg, 4mg, 6mg, 8mg, 10mg and 12mg film-coated tablets SMC No 1200/16 https://www.scottishmedicines.org.uk/files/advice/perampanel_Fycompa_Non_Sub_FINAL_Sept_2016_for_website.pdf	**Not recommended** **Indication under review:** Adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy.	**Category 4** Not available as not recommended for use in NHS Scotland
Progesterone 100mg vaginal tablets (Lutigest®) SMC No 1185/16 https://www.scottishmedicines.org.uk/files/advice/progesterone_Lutigest_FINAL_Sept_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** Luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women.	**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

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Rilpivirine/emtricitabine/tenofovir alafenamide 200mg/25mg/25mg film-coated tablets (Odefsey®) SMC No 1189/16 **Product Update** https://www.scottishmedicines.org.uk/files/advice/rilpivirine_emtricitabine_Odefsey_Abbreviated_FINAL_Sept_2016_for_website.pdf	**Accepted for use** **Indication under review:** treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg), infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV-1 RNA ≤100,000 copies/mL.	**Category 1** available in line with national guidance
Tocilizumab (RoActemra®) 162mg Solution for Injection in Pre-Filled Syringe SMC No 1201/16 https://www.scottishmedicines.org.uk/files/advice/tocilizumab_RoActemra_Non_Sub_FINAL_Sept_2016_for_website.pd	**Not recommended** **Indication under review:** Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.	**Category 4** Not available as not recommended for use in NHS Scotland
Trametinib 0.5mg and 2mg film-coated tablets (Mekinist®) SMC No 1161/16 https://www.scottishmedicines.org.uk/files/advice/trametinib_0_5mg_and_2mg_Mekinist_FINAL_August_2016_Amended_02.09.16_for_website.pdf	**Accepted for restricted use** **Indication under review:** in combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. **SMC restriction:** to first-line treatment.	**Category 6** not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Tioproprium, 2.5 micrograms, solution for inhalation (Spiriva®Respimat®) SMC No 1028/15	**Accepted for use** **Indication under review:** As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta$_2$ agonists and who experienced one or more severe exacerbations in the previous year	**Category 6** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts – 30/7/15	**Category 2** available in line with local guidance for prescribing initiated by specialist only.
https://www.scottishmedicines.org.uk/files/advice/tiotropium_Spiriva_FINAL_July_2015_for_website.pdf			
Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®) SMC No 1096/15	**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 6** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts – 3/12/15	**Category 2** available in line with local guidance for prescribing http://www.intranet.wosc an.scot.nhs.uk/guideline s-and-protocols/lung-cancer/
https://www.scottishmedicines.org.uk/files/advice/lenalidomide__Revlimid__FINAL_Nov_2015_Amended_27.11.15_for_website.pdf			

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Blinatumomab, 38.5 micrograms powder for concentrate and solution for infusion (Blincyto®) SMC No 1145/16	**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 awaiting for further advice from local clinical experts -26/5/16	**Category 2** available in line with local guidance for prescribing http://www.intranet.wosc an.scot.nhs.uk/guideline s-and-protocols/haemato-oncology/leukaemia/
https://www.scottishmedicines.org.uk/files/advice/DAD_blinatumomab_Blincyto_FINAL_May_2016_for_website.pdf			
Febuxostat 120mg film-coated tablet (Adenuric®) SMC No 1153/16	**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 awaiting for further advice from local clinical experts – 26/5/16	**Category 2** available in line with local guidance for prescribing
https://www.scottishmedicines.org.uk/files/advice/DAD_febuxostat_Adenuric_FINAL_May_2016_for_website.pdf			
Crizotinib, 200mg and 250mg hard capsule (Xalkori®) SMC No 1152/16	**Accepted for use** **Indication under review:** First-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	**Category 6** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts -28/7/16	**Category 2** available in line with local guidance for prescribing http://www.intranet.wosc an.scot.nhs.uk/guideline s-and-protocols/lung-cancer/
https://www.scottishmedicines.org.uk/files/advice/crizotinib_Xalkori_FINAL_June_2016_for_website.pdf			
Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) SMC No 1159/16	**Accepted for use** **Indication under review:** Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy.	**Category 6** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts - 28/7/16	**Category 2** available in line with local guidance for prescribing
https://www.scottishmedicines.org.uk/files/advice/secukinumab_Cosentyx_FINAL_June_2016_for_website.pdf			
Secukinumab 150mg solution for injection in pre-filled pen and pre-filled syringe (Cosentyx®) SMC No 1167/16	**Accepted for restricted use** **Indication under review:** alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **SMC restriction:** Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.	**Category 6** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts - 28/7/16	**Category 2** available in line with local guidance for prescribing
https://www.scottishmedicines.org.uk/files/advice/secukinumab_Cosentyx__sA_FINAL_July_2016_for_website.pdf			

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Isavuconazole, 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®) SMC No 1129/16	**Accepted for use within** **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 awaiting for further advice from local clinical experts - 26/5/16	**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
https://www.scottishmedicines.org.uk/files/advice/secukinumab_Cosentyx__sA_FINAL_July_2016_for_website.pdf			
Panobinostat, 10mg, 15mg and 20mg hard capsules (Farydak®) SMC No 1122/16	**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** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts - 28/1/16	**Category 2** available in line with local guidance for prescribing
https://www.scottishmedicines.org.uk/files/advice/panobinostat_Farydak_FINAL_January_2016_amended_030216_for_website.pdf			
Sorafenib 200mg film-coated tablets (Nexavar®) SMC No 482/08	**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** not routinely available as local implementation plans are being developed or the ADTC is awaiting for further advice from local clinical experts - 28/1/16	**Category 2** available in line with local guidance for prescribing
https://www.scottishmedicines.org.uk/files/advice/sorafenib_Nexavar_2nd_Resubmission_FINAL_Dec_2015_for_website.pdf			

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