August 2016
Vol. 13 No. 4

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 392 – Adalimumab for treating moderate to sever hidradenitis suppurativa	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance /392**	**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. https://www.scottishmedicines.org.uk/files/advice/adalimumab__Humira__FINAL_April_2016_for_website.pdf	**9/5/16**	**Yes**
NICE Technology Appraisal Guidance No 393 – Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance /393**	**Accepted for restricted** **Indication under review**: adults with primary hypercholesterolaemia (heterozygous familial 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 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. SMC restriction: for specialist use only in patients at high cardiovascular risk as follows: - patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, - patients with HeFH and LDL-C ≥3.5mmol/L, for secondary prevention of cardiovascular events or, - patients at high risk due to previous cardiovascular events and LDL-C ≥4.0mmol/L or, - patients with recurrent/polyvascular disease and LDL-C ≥3.5mmol/L. https://www.scottishmedicines.org.uk/files/advice/alirocumab_Praluent_FINAL_July_2016_Amended_04.08.16_for_website.pdf	**8/8/16**	**No**

NICE Technology Appraisal Guidance No 394 – Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/394**	**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. In phase III clinical studies, treatment with evolocumab added to optimised background lipid-lowering therapy significantly improved mean percentage change in LDL-C from baseline to week 12, versus placebo and another lipid-lowering treatment, in patients with heterozygous familial and non-familial hypercholesterolaemia and mixed dyslipidaemia. Addition of evolocumab to standard care also significantly reduced LDL-C versus standard care alone in patients with homozygous familial hypercholesterolaemia https://www.scottishmedicines.org.uk/files/advice/DAD_evolocumab_Repatha_FINAL_May_2016_for_website.pdf	**13/6/16**	**No**
NICE Technology Appraisal Guidance No 395 – Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/395**	**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**.** https://www.scottishmedicines.org.uk/files/advice/ceritinib__Zykadia__FINAL_Nov_2015_for_website.pdf	**7/12/15**	**No**
NICE Technology Appraisal Guidance No 396 – Trametinib in combination with darafenib for treating unresectable or metastatic melanoma	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/396**	**Forthcoming submission**	**No date yet**	**No**
NICE Technology Appraisal Guidance No 397 – Belimumab for treating active autoantibody-positive systemic lupus erythematosus	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/397**	**Not recommended** **Indication under review:** Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. https://www.scottishmedicines.org.uk/files/advice/DAD_belimumab_Benlysta_Final_March_2012_amended_300312_for_website.pdf	**9/4/12**	**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 Multiple Technology Appraisal Guidance No 390 – Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/390**	**Canagliflozin** **Accepted for restricted use** **Indication under review:** In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** to use in the following situations: • dual therapy in combination with metformin • triple therapy in combination with metformin plus standard of care • add-on to insulin therapy in combination with insulin plus standard of care https://www.scottishmedicines.org.uk/files/advice/M__Scottish_Medicine_Consortium_Web_Data_Audit_advice_Advice_by_Year_2014_No.6_-_June_2014_canaglaflozin__Invokana__FINAL_May_2014_for_website.pdf **Dapagliflozin** **Accepted for restricted use** **Indication under review**: In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction**: in triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor. https://www.scottishmedicines.org.uk/files/advice/dapagliflozin_Forxiga_2nd_Resub_FINAL_June_2014_for_website.pdf **Empagliflozin** **Accepted for restricted use** **Indication under review:** Treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy: in combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction**: to use in the following situations: • dual therapy in combination with metformin, when a sulphonylurea is inappropriate • triple therapy in combination with metformin plus standard of care • add-on to insulin therapy in combination with insulin plus standard of care https://www.scottishmedicines.org.uk/files/advice/empagliflozin__Jardiance__FINAL_Sept_2014_amended_09.10.14_for_website.pdf	**9/6/14** **7/7/14** **3/10/14**	**All included in the 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**

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
Adalimumab (Humira®) Pre-filled Pen, Pre-filled Syringe and Vial SMC No 1173/16 https://www.scottishmedicines.org.uk/files/advice/adalimumab_Humira_Non_Sub_FINAL_June_2016_for_website.pdf	**Not recommended for use** **Indication under review:** Treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy. (This licence extension relates to previous SMC advice (468/08).	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Afatinib (Giotrif®) 20 mg/30 mg/40 mg/50 mg film-coated tablets SMC No 1174/16 https://www.scottishmedicines.org.uk/files/advice/afatinib_Giotrif_Non_Sub_FINAL_June_2016_for_website.pdf	**Not recommended for use** **Indication under review:** As monotherapy for the treatment of locally advanced or metastatic non small cell lung cancer of squamous histology **progressing on or after platinum-based chemotherapy**.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Azacitidine (Vidaza®) 25 mg/ml powder for suspension for injection SMC No 1175/16 https://www.scottishmedicines.org.uk/files/advice/azacitidine_Vidaza_Non_Sub_FINAL_June_2016_for_website.pdf	**Not recommended for use** **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.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Alirocumab 75mg and 150mg solution for injection in pre-filled pen (Praluent®) SMC No 1147/16 https://www.scottishmedicines.org.uk/files/advice/alirocumab_Praluent_FINAL_July_2016_Amended_04.08.16_for_website.pdf	**Accepted for restricted use** **Indication under review:** adults with primary hypercholesterolaemia (heterozygous familial 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 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. **SMC restriction:** for specialist use only in patients at high cardiovascular risk as follows: - patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, - patients with HeFH and LDL-C ≥3.5mmol/L, for secondary prevention of cardiovascular events or, - patients at high risk due to previous cardiovascular events and	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	LDL-C ≥4.0mmol/L or, - patients with recurrent/polyvascular disease and LDL-C ≥3.5mmol/L.	
Brivaracetam 10mg, 25mg, 75mg, 100mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®) SMC No 1160/16 https://www.scottishmedicines.org.uk/files/advice/brivaracetam_Briviact_FINAL_June_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. **SMC restriction:** for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Crizotinib, 200mg and 250mg hard capsule (Xalkori®) SMC No 1152/16 https://www.scottishmedicines.org.uk/files/advice/crizotinib_Xalkori_FINAL_June_2016_for_website.pdf	**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 waiting for further advice from local clinical experts
Diamorphine hydrochloride 720 microgram/actuation and 1600 microgram/actuation nasal spray (Ayendi®) SMC No 1172/16 **Product Update** https://www.scottishmedicines.org.uk/files/advice/diamorphine_hydrochloride_Ayendi_Abb_FINAL_July_2016_for_website.pdf	**Accepted for use** **Indication under review:** treatment of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray (Ayendi®) should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring.	**Category 1** Available in line with national guidance
Elotuzumab (Empliciti®) 300mg and 400mg powder for concentrate for solution for infusion SMC No 1183/16 https://www.scottishmedicines.org.uk/files/advice/elotuzumab_Empliciti_Non_Sub_FINAL_July_2016_for_website.pdf	**Not recommended** **Indication under review:** Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in adult patients who have received at least one prior therapy.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film-coated tablets (Descovy®) SMC No 1169/16 **Product Update** https://www.scottishmedicines.org.uk/files/advice/emtricitabine_tenofovir_Descovy_Abb_FINAL_July_2016_for_website.pdf	**Accepted for use** **Indication under review:** in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Human alpha$_1$-proteinase inhibitor 1,000mg powder and solvent for solution for infusion (Respreeza®) SMC No 1157/16 https://www.scottishmedicines.org.uk/files/advice/human_alpha_1_proteinase_inhibitor_Respreeza_FINAL_July_2016_Updated_180716_for_website.pdf	**Not recommended for use** **Indication under review:** For maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha$_1$-proteinase inhibitor (A1-PI) deficiency.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Insulin degludec (Tresiba®) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen SMC No. (856/13) **2nd Resubmission** https://www.scottishmedicines.org.uk/files/advice/insulin_degludec_Tresiba_2ndResub_FINAL_July_2016_Updated_30.07.16_for_website.pdf	**Accepted for use** **Indication under review:** treatment of diabetes mellitus in adults.	**Category 1** Available in line with national guidance
Ibrutinib 140mg hard capsule (Imbruvica®) SMC No 1150/16 https://www.scottishmedicines.org.uk/files/advice/ibrutinib_Imbruvica_MCL_FINAL_July_2016_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Ibrutinib 140mg hard capsule (Imbruvica®) SMC No 1151/16 https://www.scottishmedicines.org.uk/files/advice/ibrutinib_Imbruvica_CLL_FINAL_July_2016_Amended_30.07.16_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. **SMC restriction:** patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Levofloxacin 240mg nebuliser solution (Quinsair®) SMC No 1162/16 https://www.scottishmedicines.org.uk/files/advice/levofloxacin_Quinsair_FINAL_June_2016_Updated_30.07.16_for_website.pdf	**Accepted for restricted use** **Indication under review:** the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis. **SMC restriction:** for use as a third line treatment option after colistimethate sodium (first line) and tobramycin (second line).	**Category 1** Available in line with national guidance Continuation of treatment from a specialist centre
Mepolizumab 100mg powder for solution for injection (Nucala®) SMC No 1149/16 **Amended Advice** https://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 x 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 from local clinical experts

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Necitumumab (Portrazza®) 800mg concentrate for solution for infusion SMC No 1184/16 https://www.scottishmedicines.org.uk/files/advice/necitumumab_Portazza_Non_Sub_FINAL_July_2016_for_website.pdf	**Not recommended** **Indication under review:** in combination with gemcitabine and cisplatin chemotherapy for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer who have not received prior chemotherapy for this condition.	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No 1120/16 **2nd Resubmission** https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_Melanoma_Resub_FINAL_July_2016_Amended_04.08.16_for_website.pdf	**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.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Nivolumab 40mg/4mL and 100mg/10mL vials of concentrate for solution for infusion (Opdivo®) SMC No 1144/16 https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_FINAL_June_2016_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Ramucirumab (Cyramza®) 10 mg/ml concentrate for solution for infusion®) SMC No 1176/16 https://www.scottishmedicines.org.uk/files/advice/ramucirumab_Cyramza_Non_Sub_FINAL_June_2016_for_website.pdf	**Not recommended for use** **Indications under review:** • In combination with paclitaxel for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy • As monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate	**Category 4** Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included
Rilpivirine 25mg film-coated tablet (Edurant®) SMC No 1168/16 https://www.scottishmedicines.org.uk/files/advice/rilpivirine_hydrochloride_Edurant_Abb_FINAL_July_2016_for_website.pdf	**Accepted for use** **Indication under review:** in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL) ≤ 100,000 HIV-1 RNA copies/mL.	**Category 1** Available in line with national guidance
Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) SMC No 1159/16 https://www.scottishmedicines.org.uk/files/advice/secukinumab_Cosentyx_FINAL_June_2016_for_website.pdf	**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 waiting for further advice from local clinical experts
Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) SMC No 1167/16 **Amended advice** https://www.scottishmedicin	**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	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
es.org.uk/files/advice/secukinumab_Cosentyx__sA_FINAL_July_2016_for_website.pdf	adequate trials of at least two standard DMARDs either individually or in combination.	waiting for further advice from local clinical experts
Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®) SMC No 1158/16 https://www.scottishmedicines.org.uk/files/advice/vortioxetine_Brintellix_FINAL_June_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of major depressive episodes in adults. **SMC restriction:** patients who have experienced an inadequate response (either due to lack of adequate efficacy and/or safety concerns/intolerability) to two or more previous antidepressants	**Category 6** Not routinely available as local implementation plans are being developed or the 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
Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) SMC No 1135/16 https://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 26/5/16	**Category 2** Available in line with local guidance
Camellia sinensis (green tea) leaf extract 10% ointment (Catephen®) SMC No 1133/16 https://www.scottishmedicines.org.uk/files/advice/camellia_sinensis_green_tea_leaf_Catephen_FINAL_March_2016_for_website.pdf	**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.	Category 6 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
Ceritinib 150mg hard capsules (Zykadia®) SMC No 1097/15 https://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 3/12/15	**Category 2** Available in line with local guidance
Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate (Genvoya®) SMC No 1142/16 https://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 26/5/16	**Category 1** Available in line with national guidance
Enzalutimide 40mg soft capsule (Xtandi®) SMC No 1066/15 https://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 3/12/15	**Category 2** Available in line with local guidance

Drug (approved by SMC)	SMC Advice	Previous decision and date	Updated FV Formulary position
Glatiramer acetate 40mg/mL (Copaxone®) https://www.scottishmedicines.org.uk/files/advice/glatiramer_acetate__Copaxane__Abbreviated_FINAL_Nov_2015_for_website.pdf	**Accepted for use** **Indication under review**: treatment of relapsing forms of multiple sclerosis (MS).	Category 6 3/12/16	**Category 1** Available in line with national guidance
Naloxegol 12mg and 25mg film-coated tablets (Moventig®) SMC No 1106/15 https://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 3/12/15	**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
Sacubitril/valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film coated tablet (Entresto®) SMC No 1132/16 https://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 10/3/16	**Category 1** Available in line with national guidance
Ulipristal acetate (Esmya®) SMC No 1128/16 https://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 10/3/16	**Category 1** Available in line with national guidance

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