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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://guidelines.staffnet.fv.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.

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
No submissions				

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 MTA Guidance **No 449** Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease	**Refer to NICE documentation for full guidance** **www.nice.org.uk/guidance/449**	**Everolimus** **Accepted for use** **Indication under review:** for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease. **Sunitinib** **Accepted for use** **Indication under review**: treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults.	**13/1/17** **8/4/11**	**Yes –** in section 8.1.5 – other antineoplastic drugs **Yes** – in section 8.1.5 – other antineoplastic drugs
NICE MTA Guidance **No 455** Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people	**Refer to NICE documentation for full guidance** **www.nice.org.uk/guidance/455**	**Adalimumab** **Accepted for restricted** **Indication under review:** treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. **SMC restriction**: patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score of ≥10 and a Dermatology Life Quality Index (DLQI) of >10. **Etanercept** **Accepted for restricted use** **Indication under review**: for the treatment of chronic sever plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other therapies or phototherapies **Ustekinumab** **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. **SMC restriction**: continued treatment should be restricted to patients who achieve at least 75% improvement in their Psoriasis Area and Severity Index (PASI 75) within 16 weeks	**5/6/15** **7/8/09** **4/12/15**	**Yes –** in sections 1.5.2 – drugs affecting the immune response. 10.1.3 -Drugs which suppress the rheumatic disease process. 13.5.3 – Drugs affecting the immune response **Yes –** in sections 10.1.3 -Drugs which suppress the rheumatic disease process. 13.5.3 – Drugs affecting the immune response **Yes –** in sections 10.1.3 -Drugs which suppress the rheumatic disease process. 13.5.3 – Drugs affecting the immune response
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 MTA Guidance **No 459** Collagenase clostridium histolyticum for treating Dupuytren's contracture	**Refer to NICE documentation for full guidance** **www.nice.org.uk/guidance/459**	**Accepted for restricted use** **Indication under review:** treatment of Dupuytren's contracture in adult patients with a palpable cord. **SMC restriction**: restricted to use as an alternative to limited fasciectomy in adult patients with Dupuytren's contracture of moderate severity (as defined by the British Society for Surgery of the hand (BSSH), with palpable cord and up to two affected joints per hand, who are suitable for limited fasciectomy, but for whom percutaneous needle fasciotomy is not considered a suitable treatment option.		**Yes** – in section 10.3.1 – Drugs for the relief of soft-tissue disorders and topical pain relief
NICE MTA Guidance **No 460** Adalimumab and dexamethasone for treating non-infectious uveitis	**Refer to NICE documentation for full guidance** **www.nice.org.uk/guidance/460**	**Not recommended** **Indication under review:** treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had as inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.	**7/10/16**	**Yes –** in sections 1.5.2 – drugs affecting the immune response. 10.1.3 -Drugs which suppress the rheumatic disease process. 13.5.3 – Drugs affecting the immune response

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

The ADTC recommends that prescribers may prescribe these drugs in accordance with SMC advice, unless they are not recommended by SMC

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Adalimumab 40mg/0.4mg pre-filled syringe and pre-filled pen / adalimumab 40mg/0.4ml 40mg/0.8ml vial for paediatric use (Humira®) SMC No 1305/18 https://www.scottishmedicines.org.uk/files/advice/adalimumab_Humira_Non_Sub_FINAL_Dec_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.	**Category 4** **Not recommended for use in Scotland by SMC**
5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz) SMC No 1260/17 https://www.scottishmedicines.org.uk/media/3088/5-aminolaevulinic_acid_ameluz_resubmission_final_jan_0218_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of superficial and / or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and / or poor cosmetic outcome in adults.	**Category 1** Available in line with national guidance
Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) SMC No 1297/18 https://www.scottishmedicines.org.uk/media/3134/atezolizumab-tecentriq-for-uc-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy or who are considered cisplatin ineligible.	**Category 4** **Not recommended for use in Scotland by SMC**
Brodalumab 210mg solution for injection in a pre-filled syringe (Kyntheum®) SMC No 1283/17 https://www.scottishmedicines.org.uk/files/advice/brodalumab_Kyntheum_FINAL_Nov_2017_Amended_06.12.17_Website.pdf	**Not recommended** **Indication under review:** For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.	**Category 4** **Not recommended for use in Scotland by SMC**
Carbetocin 100 micrograms/mL solution for injection (Pabal®) SMC No 309/06 https://www.scottishmedicines.org.uk/files/advice/carbetocin_Pabal_FINAL_Dec_2017_for_website.pdf	**Not recommended** **Indication under review:** For the prevention of uterine atony following delivery of the infant by Caesarean section under epidural or spinal anaesthesia	**Category 4** **Not recommended for use in Scotland by SMC**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ceftaroline fosamil 600mg powder for concentrate for solution for infusion (Zinforo®) SMC No 1306/18 https://www.scottishmedicines.org.uk/files/advice/ceftaroline_fosamil_Zinforo_Non_Sub_FINAL_Dec_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of: • Complicated skin and soft tissue infections in children from age 2 months • Community-acquired pneumonia in children from age of 2 months	**Category 4** **Not recommended for use in Scotland by SMC**
Ceftazidime/avibactam 2g/0.5g powder for concentrate for solution for infusion (Zavicefta®) SMC No 1307/18 https://www.scottishmedicines.org.uk/files/advice/ceftazidime_avibactam__Zavicefta__Non_Sub_FINAL_Dec_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of the following indications in adults: • Complicated intra-abdominal infection (cIAI) • Complicated urinary tract infection (cUTI) • Hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP) • Infections due to aerobic Gram-negative organisms in adult patients with limited treatment options	**Category 4** **Not recommended for use in Scotland by SMC**
Ceritinib 150mg hard capsules (Zykadia®) SMC No 1333/18 https://www.scottishmedicines.org.uk/media/3275/ceritinib-zykadia-non-sub-final-march-2018-for-website.pdf	**Not recommended** **Indication under review:** As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer.	**Category 4** **Not recommended for use in Scotland by SMC**
Ciprofloxacin ear drops solution, single dose container 2mg/mL (Cetraxal®) SMC No 1320/18 https://www.scottishmedicines.org.uk/media/3276/ciprofloxacin-eardrops-cetraxal-abbreviated-final-march-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** treatment of acute otitis externa in adults and children older than 1 year with an intact tympanic membrane, caused by ciprofloxacin susceptible microorganisms. **SMC restriction:** when off-label or unlicensed ciprofloxacin formulations would otherwise be used.	**Category 1** Available in line with national guidance
Cladribine 10mg tablet (Mavenclad®) SMC No 1300/18 https://www.scottishmedicines.org.uk/media/3097/cladribine_mavenclad_final_jan_2018_amended_070218_for_website.pdf	**Accepted for restricted use** **Indication under review:**. treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features. **SMC restriction:** • Patients with rapidly evolving severe relapsing-remitting MS: patients with two or more relapses in the prior year whether on treatment or not, and at least one T1 gadolinium-enhancing lesion. • Patients with sub-optimal therapy relapsing-remitting MS: patients with one or more relapses in the previous year while on disease modifying therapy, and at least one T1 gadolinium-enhancing lesion or nine T2 lesions.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Clostridium botulinum type A toxin-haemagglutinin complex 300 and 500 units (Dysport®) SMC No 1321/18 https://www.scottishmedicines.org.uk/media/3135/clostridium-botulinum-toxin-type-a-dysport-non-sub-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** Symptomatic treatment of focal spasticity of lower limbs in adults affecting the ankle joint due to stroke or traumatic brain injury.	**Category 4** **Not recommended for use in Scotland by SMC**
Daptomycin 350mg and 500mg powder for solution for injection or infusion (Cubicin®) SMC No 1309/18 https://www.scottishmedicines.org.uk/media/3098/daptomicin_cubicin_non_sub_final_jan_2018_for_website.pdf	**Not recommended** **Indication under review:** Treatment of paediatric (1 to 17 years of age) patients with *Staphylococcus aureus* bacteraemia associated with complicated skin and soft-tissue infections.	**Category 4** **Not recommended for use in Scotland by SMC**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Dimethyl fumarate 30mg and 120mg gastro-resistant tablets (Skilarence®) SMC No 1313/18 https://www.scottishmedicines.org.uk/media/3277/dimethyl-fumarate-skilarence-final-march-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy. **SMC restriction:** for use in patients in whom other non-biologic systemic treatments (methotrexate, ciclosporin and acitretin) are not appropriate or have failed and who are considered unsuitable for biologic therapy given their current disease state or personal preference.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Dexamethasone 40mg tablets (Neofordex®) SMC No 1322/18 https://www.scottishmedicines.org.uk/media/3136/dexamethasone-neofordex-non-sub-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** In adults for the treatment of symptomatic multiple myeloma in combination with other medicinal products	**Category 4** **Not recommended for use in Scotland by SMC**
Darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®) SMC No 1290/18 https://www.scottishmedicines.org.uk/files/advice/darunavir_Symtuza_Abbreviated_FINAL_Dec_2017_for_website.pdf	**Product Update** **Accepted for use** **Indication under review:** the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40kg).	**Category 1** Available in line with national guidance
Eliglustat 84mg hard capsules (Cerdelga®) SMC No 1277/17 https://www.scottishmedicines.org.uk/files/advice/eliglustat_Cerdelga_FINAL_Nov_2017_Website.pdf	**Advice: following a full submission considered under the ultra-orphan process** **Accepted for use** **Indication under review**: for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolisers, intermediate metabolisers or extensive metabolisers.	**Following a full submission considered under the ultra-orphan process** **Category 3 –** available from a specialist centre
Eluxadoline, 75mg and 100mg film-coated tablets (Truberzi®) SMC No 1292/18 https://www.scottishmedicines.org.uk/media/3101/eluxadoline_truberzi_final_dec_2017_amended_141217_for_website.pdf	**Not recommended** **Indication under review:** in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D).	**Category 4** **Not recommended for use in Scotland by SMC**
Elvitegravir 150mg / cobicistat 150mg / emtricitabine 200mg / tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Stribild®) SMC No 1310/18 https://www.scottishmedicines.org.uk/media/3102/elvit_cobic_emtric_stribild_non_sub_final_jan_2018_with_website.pdf	**Not recommended** **Indication under review:** Treatment of HIV-1 infection in adolescents aged 12 to <18 years weighing ≥35kg who are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild® and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil fumarate.	**Category 4** **Not recommended for use in Scotland by SMC**
Elvitegravir 150mg / cobicistat 150mg / emtricitabine 200mg / tenofovir alafenamide 10mg (Genvoya®) SMC No 1323/18 https://www.scottishmedicines.org.uk/media/3137/elvitegravir-genvoya-non-sub-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** Treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in children aged from 6 years and with body weight at least 25 kg for whom alternative regimens are unsuitable due to toxicities.	**Category 4** **Not recommended for use in Scotland by SMC**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Fluticasone furoate, umeclidinium, vilanterol (as trifenatate) 92 micrograms /55 micrograms / 22 micrograms inhalation powder (Trelegy® Ellipta®) SMC No 1303/18 **Product Update** https://www.scottishmedicines.org.uk/media/3104/fluticasone_furoate_trelegy_ellipta_abbreviated_final_jan_2018_for_website.pdf	**Accepted for restricted use** **Indication under review:** maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist. **SMC restriction:** in patients with severe COPD (forced expiratory volume in one second [FEV_1] <50% predicted normal).	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Lacosamide, 50mg, 100mg, 150mg, 200mg tablets, 10mg/mL syrup and 10mg/mL solution for intravenous infusion (Vimpat®) SMC No 1301/18 https://www.scottishmedicines.org.uk/media/3108/lacosamide_vimpat_abbreviated_final_jan_2018_for_website.pdf	**Product Update** **Accepted for restricted use** **Indication under review**: as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adolescents and children from 4 years of age with epilepsy. **SMC restriction:** patients with refractory epilepsy. Treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	**Category 2** Available in line with local guidance for prescribing
Lacosamide, 50mg, 100mg, 150mg, 200mg tablets, 10mg/mL syrup and 10mg/mL solution for intravenous infusion (Vimpat®) SMC No 1324/18 https://www.scottishmedicines.org.uk/media/3138/lacosamide-vimpat-non-sub-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** As monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adolescents and children from 4 years of age with epilepsy.	**Category 4** **Not recommended for use in Scotland by SMC**
Levonorgestrel 19.5mg intrauterine delivery system (Kyleena®) SMC No 1299/18 https://www.scottishmedicines.org.uk/media/3109/levonorgestrel_kyleena_final_jan_2018_for_website.pdf	**Accepted for use** **Indication under review:** contraception for up to 5 years.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Lopinavir 80mg, ritonavir 20mg oral solution (Kaletra®) SMC No 1302/18 **Product Update** https://www.scottishmedicines.org.uk/media/3110/lopinavir-ritonavir_kaletra_abb_final_jan_2018_for_website.pdf	**Accepted for use** **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to ≤2 years.	**Category 3** Available from a specialist centre
Metformin hydrochloride 500mg, 750mg and 1000mg prolonged release tablets (Glucophage SR®) SMC No 1308/18 https://www.scottishmedicines.org.uk/files/advice/metformin_hydrochloride_Glucophage_Non_Sub_FINAL_Dec_2017_for_website.pdf	**Not recommended** **Indication under review:** Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with impaired glucose intolerance and/or impaired fasting glucose, and or increased $HbA1_C$ who are: • At high risk for developing overt type 2 diabetes mellitus and • Still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle change for to 6 months	**Category 4** **Not recommended for use in Scotland by SMC**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Nilotinib 150mg and 200mg hard capsules (Tasigna®) SMC No 1325/18 https://www.scottishmedicines.org.uk/media/3139/nilotinib-tasigna-non-sub-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** • paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase • paediatric patients with Philadelphia chromosome positive CML in chronic phase with resistance or intolerance to prior therapy including imatinib	**Category 4** **Not recommended for use in Scotland by SMC**
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No 1285/18 https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opvido_FINAL_Dec_2017_for_website.pdf	**Not recommended** **Indication under review:** Nivolumab as monotherapy is indicated for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy	**Category 4** **Not recommended for use in Scotland by SMC**
Obinutuzumab, 1,000mg, concentrate for solution for infusion (Gazyvaro®) SMC No 1286/18 https://www.scottishmedicines.org.uk/media/3115/obinutuzumab_gazyvaro_final_dec_2018_amended_141217_for_website.pdf	**Not recommended** **Indication under review:** Obinutuzumab in combination with chemotherapy, followed by obinutuzumab maintenance therapy in patients achieving a response, for the treatment of patients with previously untreated advanced follicular lymphoma.	**Category 4** **Not recommended for use in Scotland by SMC**
Parathyroid hormone 25, 50, 75 and 100 micrograms/dose powder and solvent for solution for injection (Natpar®) SMC No 1334/18 https://www.scottishmedicines.org.uk/media/3278/parathyroid-hormone-natpar-non-sub-final-march-2018-for-website.pdf	**Not recommended** **Indication under review:** As adjunctive treatment of adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone.	**Category 4** **Not recommended for use in Scotland by SMC**
Pasireotide (as pamoate) 10, 20, 30 and 40mg powder and solvent for suspension for injection (Signifor®) SMC No 1311/18 https://www.scottishmedicines.org.uk/media/3118/pasireotide_signifor_non_sub_final_jan_2018_for_website.pdf	**Not recommended** **Indication under review:** Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.	**Category 4** **Not recommended for use in Scotland by SMC**
Peginterferon alfa-2a 135 micrograms and 180 micrograms solution for injection in pre-filled pen / peginterferon alfa-2a 90 micrograms, 135 micrograms and 180 micrograms solution for injection in pre-filled syringe (Pegasys®) SMC No 1312/18 https://www.scottishmedicines.org.uk/media/3119/peginterferon_alfa-2a_pegasys_non_sub_final_jan_2018_for_website.pdf	**Not recommended** **Indication under review:** Treatment of hepatitis B envelope antigen (HBeAg)-positive chronic hepatitis B in non-cirrhotic children and adolescents 3 years of age and older with evidence of viral replication and persistently elevated serum ALT levels.	**Category 4** **Not recommended for use in Scotland by SMC**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1291/18 https://www.scottishmedicines.org.uk/media/3121/pembrolizumab_keytruda_final_jan_2018_for_website.pdf	**Accepted for restricted use** **Indication under review:** as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	**Category 1** Available in line with national guidance
Pembrolizumab (Keytruda®) 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion SMC No 1296/18 https://www.scottishmedicines.org.uk/media/3140/pembrolizumab-keytruda-chl-final-feb-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a phase II study, pembrolizumab was associated with a clinically meaningful overall response rate in adults with classical Hodgkin lymphoma who had failed autologous stem cell transplant and brentuximab vedotin, or who were transplant-ineligible and had failed brentuximab vedotin.	**Category 1** Available in line with national guidance
Recombinant E.coli asparaginase 10,000 units powder for concentrate for solution for infusion (Spectrila®) SMC No 1319/18 **Product Update** https://www.scottishmedicines.org.uk/media/3274/asparaginase-spectrila-abbreviated-final-march-2018-for-website.pdf	**Accepted for use** **Indication under review:** as a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adults.	**Category 3** Available from a specialist centre in another NHS Board
Ribociclib 200mg film-coated tablets (Kisqali®) SMC No 1295/18 https://www.scottishmedicines.org.uk/media/3141/ribociclib-kisqali-final-feb-2018-for-website.pdf	**Accepted for use** **Indication under review:** In combination with an aromatase inhibitor, for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer as initial endocrine-based therapy.	**Category 1** Available in line with national guidance
Sarilumab 150mg and 200mg solution for injection in pre-filled syringe and pre-filled pen (Kevzara®) SMC No 1314/18 https://www.scottishmedicines.org.uk/media/3270/sarilumab-kevzara-final-march-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** in combination with methotrexate for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Sarilumab can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate. **SMC restriction:** in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a TNF antagonist, it may be used in patients ineligible to receive rituximab.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Sevelamer carbonate 2.4g powder for oral suspension (Renvela®) SMC No 1304/18 **Product Update** https://www.scottishmedicines.org.uk/media/3124/sevelamer_carbonate_renvela_abbreviated_final_jan_2018_for_website.pdf	**Accepted for restricted use** **Indication under review:** control of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area of >0.75m^2) with chronic kidney disease.	**Category 3** Available from a specialist centre

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Sofosbuvir 400mg film-coated tablets (Sovaldi®) SMC No 1326/18 https://www.scottishmedicines.org.uk/media/3142/sofosbuvir-solvadi-non-sub-final-feb-2018-for-website.pdf	**Not recommended** **Indication under review:** In combination with other medicinal products for the treatment of chronic hepatitis C in adolescents aged 12 to <18 years.	**Category 4** **Not recommended for use in Scotland by SMC**
Sofosbuvir 400mg, velpatasvir 100mg, voxilaprevir 100mg film-coated tablet (Vosevi®) SMC No 1317/18 https://www.scottishmedicines.org.uk/media/3271/sofosbuvir-velpatasvir-voxilaprevir-vosevi-final-march-2018-amended-030418-for-website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** for patients who: (1) Have failed to achieve a sustained virologic response (SVR) with a direct-acting anti-viral (DAA) or (2) are DAA-naïve, have genotype 3 (GT3) HCV infection, with or without cirrhosis, and are suitable for treatment with an eight-week course.	**Category 1** Available in line with national guidance
Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) SMC No 1271/17 **Resubmission** https://www.scottishmedicines.org.uk/media/2316/sofosbuvir_velpatasvir_epclusa_final_sept_2017_051017_amended_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** in patients with genotype 1 or 4 HCV infection.	**Category 1** Available in line with national guidance
Teduglutide 5mg and 1.25mg vials of powder and solvent for solution for injection (Revestive®) SMC No 1139/16 https://www.scottishmedicines.org.uk/media/2363/teduglutide_revestive_non_sub_final_jan_2016_for_website.pdf	**Accepted for restricted use** **Indication under review:** for the treatment of patients aged one year and above with short bowel syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery. **SMC restriction:** initiation in paediatric patients (aged 1 to 17 years).	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Tofacitinib citrate 5mg film-coated tablets (Xeljanz®) SMC No 1298/18 https://www.scottishmedicines.org.uk/media/3126/tofacitinib_xeljanz_final_jan_2018_amended_050217_for_website.pdf	**Accepted for restricted use** **Indication under review:** In combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Tofacitinib can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate. **SMC restriction:** In patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a tumour necrosis factor (TNF) antagonist, it may be used in patients ineligible to receive rituximab.	**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	Updated FV Formulary position
Belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) **SMC No 775/12** https://www.scottishmedicines.org.uk/files/advice/belimumab_Benlysta_Resub_FINAL_April_2017_for_website.pdf	**Accepted for restricted use** **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. **SMC restriction:** patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Currently 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 **Pending Category 1** Available in line with national guidance
Ciprofloxacin 3mg/mL + dexamethasone 1mg/mL ear drops (Cilodex®) **SMC No 1256/17** https://www.scottishmedicines.org.uk/media/1475/ciprofloxacin-dexamethasone_cilodex_abbreviated_final_june_2017_for_website.pdf	**Accepted for restricted use** **Indication under review**: treatment of the following infections in adults and Children: Acute otitis media in patients with tympanostomyu tubes (AOMT) Acute otitis externa **SMC restriction:** treatment of acute otitis media in patients with tympanostomy tubes (AOMT)	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 1** Available in line with national guidance
Desmopressin 25 microgram, 50 microgram oral lyophilisate (Noqdirna®) **SMC No (1218/17**) https://www.scottishmedicines.org.uk/files/advice/desmopressin_Noqdirna_Resubmission_FINAL_July_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. **SMC restriction:** for use in patients aged 65 years and over	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Currently 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 **Pending Category 1** Available in line with national guidance
Dequalinium chloride 10mg vaginal tablets (Fluomizin®) **SMC No 1194/16** https://www.scottishmedicines.org.uk/media/1551/dequalinium_fluomizin_final_oct_2016_amended_311016_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of bacterial vaginosis. **SMC restriction:** in patients for whom the initial treatment is not effective or well tolerated.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 1** Available in line with national guidance
Glycopyrronium 320 micrograms/mL (glycopyrronium bromide 400 micrograms/mL oral solution (Sialanar®) **SMC No 1254/17** https://www.scottishmedicines.org.uk/media/1781/glycopyrronium_bromide_sialanar_abbreviated_final_june_2017_for_website.pdf	**Accepted for use** **Indication under review:** symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**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	Previous decision	Updated FV Formulary position
Ixekizumab 80mg solution for injection (Taltz®) SMC No 1223/17 https://www.scottishmedicines.org.uk/files/advice/ixekizumab_Taltz_FINAL_March_2017_Amended_05.04.17_for_website.pdf	Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by 28/9/17	**Currently 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 **Pending Category 2** Available in line with local guidance for prescribing

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