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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
No submissions				

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
Cardiology		
Selexipag, 200 microgram, 400 microgram, 600 microgram, 800 microgram, 1,000 microgram, 1,200 microgram, 1,400 microgram, 1,600 microgram film-coated tablets (Uptravi®) SMC No 1235/17 **Resubmission** https://www.scottishmedicines.org.uk/media/3416/selexipag-uptravi-resubmission-final-april-2018-amended-270418-for-website.pdf	Accepted for restricted use **Indication under review:** For the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II to III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. **SMC restriction:** combination therapy in a sub-population of patients with PAH specifically those in WHO FC III who are insufficiently controlled with an ERA and a PDE-5 inhibitor and who would be considered for treatment with inhaled iloprost	**Category 3** Available from a specialist centre in another NHS Board

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Dermatology		
Brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®) SMC No 1283/17 **Re-Submission** https://www.scottishmedicines.org.uk/media/3404/brodalumab-kyntheum-resubmission-final-april-2018-amended-240418-for-website.pdf	**Accepted for restricted use** **Indication under review:** for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. **SMC restriction:** for 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
Guselkumab 100mg solution for injection (Tremfya®) SMC No 1340/18 https://www.scottishmedicines.org.uk/media/3473/guselkumab-tremfya-final-may-2018-amended-060618-for-website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** for patients who have failed to respond to conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication 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
Gynaecology		
Progesterone 25mg solution for injection (Lubion®) SMC 2017 **Product Update** https://www.scottishmedicines.org.uk/media/3560/progesterone-lubion-abbreviated-final-june-2018-for-website.pdf	**Accepted for use** **Indication under review:** in adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations.	**Category 3** Available from a specialist centre in another NHS Board
Hepatology		
Ledipasvir/sofosbuvir 90mg/400mg film-coated tablet (Harvoni®) SMC No 1343/18 **Product Update** https://www.scottishmedicines.org.uk/media/3470/ledispavir-sofosbuvir-harvoni-abb-final-may-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** treatment of chronic hepatitis C (CHC) in adolescents aged 12 to <18 years. **SMC restriction:** genotype 1 and 4 CHC only.	**Category 1** Available in line with national guidance
Sofosbuvir 400mg, velpatasvir 100mg, voxilaprevir 100mg film-coated tablet (Vosevi®) SMC No 1317/18 **Amended Advice** 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
Neurology		
Eslicarbazepine acetate 200mg and 800mg tablets (Zebinix®) SMC 2090 https://www.scottishmedicines.org.uk/media/3466/eslicarbazepine-acetate-zebinix-non-sub-for-website.pdf	**Not recommended** **Indication under review:** As monotherapy in the treatment of partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Everolimus 2mg, 3mg and 5mg dispersible tablets (Votubia®) SMC No 1331/18 https://www.scottishmedicines.org.uk/media/3467/everolimus-votubia-final-may-2018-for-website.pdf	**Accepted for use** **Indication under review:** Adjunctive treatment of patients aged two years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC).	**Category 3** Available from a specialist centre in another NHS Board
Ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®) SMC No 1344/18 https://www.scottishmedicines.org.uk/media/3603/ocrelizumab-ocrevus-final-june-2018-for-website.pdf	**Not recommended** **Indication under review:** The treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.	**Category 4** Not available as not recommended for use in NHS Scotland
Oncology		
Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) SMC No 1336/18 https://www.scottishmedicines.org.uk/media/3554/atezolizumab-tecentriq-final-june-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** As monotherapy for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (*EGFR*) activating mutations or anaplastic lymphoma kinase (*ALK*)-positive tumour mutations should also have received targeted therapy before receiving atezolizumab. **SMC restriction:** treatment with atezolizumab is subject to a two-year clinical stopping rule.	**Category 1** Available in line with national guidance
Avelumab 20mg/mL concentrate for solution for infusion (Bavencio®) SMC No 1315/18 https://www.scottishmedicines.org.uk/media/3410/avelumab-bavencio-final-april-2018-for-website.pdf	**Accepted for use** **Indication under review:** As monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (mMCC).	**Category 1** Available in line with national guidance
Brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris ®) SMC No 2085 https://www.scottishmedicines.org.uk/media/3403/brentuximab-vedotin-adcetris-non-sub-final-april-2018-for-website.pdf	**Not recommended** **Indication under review:** Treatment of adult patients with CD30+ Hodgkin lymphoma at increased risk of relapse or progression following autologous stem cell transplant.	**Category 4** Not available as not recommended for use in NHS Scotland
Brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris ®) SMC 2098 https://www.scottishmedicines.org.uk/media/3555/brentuximab-adcetris-non-sub-final-june-2018-for-website.pdf	**Not recommended** **Indication under review:** treatment of adult patients with CD30+ cutaneous T-cell lymphoma after at least one prior systemic therapy.	**Category 4** Not available as not recommended for use in NHS Scotland
Crizotinib 200mg and 250mg hard capsules (Xalkori®) SMC No 1329/18 https://www.scottishmedicines.org.uk/media/3465/crizotinib-xalkori-final-may-2018-for-website.pdf	**Accepted for use** **Indication under review:** treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC).	**Category 1** Available in line with national guidance
Inotuzumab ozogamicin 1mg powder for concentrate for solution for infusion (BESPONSA®) SMC No 1328/18 https://www.scottishmedicines.org.uk/media/3469/inotuzuma	**Accepted for restricted use** **Indication under review:** as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive relapsed or refractory B cell precursor ALL should have failed treatment with at least one tyrosine kinase inhibitor. **SMC restriction:** in patients for whom the intent is to proceed to stem cell transplantation.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
b-ozogamicin-besponsa-final-may-2018-for-website.pdf		
Ixazomib 2.3mg, 3mg and 4mg hard capsules (Ninlaro®) SMC 2099 https://www.scottishmedicines.org.uk/media/3556/ixazomib-ninlaro-non-sub-final-june-2018-for-website.pdf	**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
Lutetium (^{177}Lu) oxodotreotide 370MBq/mL solution for infusion (Lutathera®) SMC No 1337/18 https://www.scottishmedicines.org.uk/media/3557/lutetium-177lu-oxodotreotide-lutathera-final-june-2018-for-website.pdf	**Indication under review:** for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults.	**Category 1** Available in line with national guidance
Midostaurin 25mg soft capsules (Rydapt®) SMC No 1330/18 https://www.scottishmedicines.org.uk/media/3471/midostaurin-rydapt-final-may-2018-for-website.pdf	**Not recommended** **Indication under review:** In combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FMS-like tyrosine kinase 3 (FLT3) mutation-positive.	**Category 4** Not available as not recommended for use in NHS Scotland
Regorafenib 40mg film-coated tablets (Stivarga®) SMC No 1316/18 https://www.scottishmedicines.org.uk/media/3408/regorafenib-stivarga-final-april-2018-for-website.pdf	**Accepted for use** **Indication under review:** as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib.	**Category 1** Available in line with national guidance
Telotristat ethyl 250mg film-coated tablets (Xermelo®) SMC No 1327/18 https://www.scottishmedicines.org.uk/media/3472/telotristat-ethyl-xermelo-final-may-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of carcinoid syndrome diarrhoea in combination with somatostatin analogue therapy in adults inadequately controlled by somatostatin analogue therapy. **SMC restriction:** patients with CS diarrhoea who experience an average of four or more bowel motions per day, despite receiving somatostatin analogue therapy.	**Category 1** Available in line with national guidance
Tivozanib 890 micrograms and 1,340 micrograms hard capsules, (Fotivda®) SMC No 1335/18 https://www.scottishmedicines.org.uk/media/3562/tivozanib-fotivda-final-june-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** the first-line treatment of adult patients with advanced renal cell carcinoma and for adult patients who are vascular endothelial growth factor receptor and mammalian target of rapamycin pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for advanced renal cell carcinoma (RCC). **SMC restriction:** to first-line treatment of advanced RCC.	**Category 1** Available in line with national guidance
Paediatrics		
Icatibant acetate, 30mg, solution for injection in pre-filled syringe (Firazyr®) SMC No 1332/18 **Product Update** https://www.scottishmedicines.org.uk/media/3405/icatibant-acetate-firazyr-abbreviated-final-april-2018-for-website.pdf	**Accepted for use** **Indication under review:** symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency. SMC has previously accepted icatibant acetate for use in adults.	**Category 2** Available in line with local guidance for prescribing

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Raltegravir 100mg granules for oral suspension (Isentress®) SMC No 2101	**Not recommended** **Indication under review:** in combination with other anti-retroviral medicinal products in the treatment of human immunodeficiency virus in neonates.	**Category 4** Not available as not recommended for use in NHS Scotland
Weight Management		
Naltrexone hydrochloride / bupropion hydrochloride 8mg / 90mg prolonged-release tablets (Mysimba®) SMC No 2086	**Not recommended** **Indication under review:** As an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index (BMI) of • ≥ 30 kg/m² (obese), or • ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension)	**Category 4** Not available as not recommended for use in NHS Scotland

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Dermatology			
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	**Category 2** Available in line with local guidance for prescribing
Opthalmology			
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 2** Available in line with local guidance for prescribing
Paediatrics			
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/3273/teduglutide-revestive-final-jan-2018-revised-060318-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	**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
Respiratory			
Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 87 micrograms / 5 micrograms / 9 micrograms metered dose inhaler (Trimbow®) SMC No 1274/17 https://www.scottishmedicines.org.uk/media/1299/beclometasone_trimbow_abbreviated_final_sept_2107_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 beta2-agonist. **SMC restriction:** severe COPD (forced expiratory volume in one second less than 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	**Category 2** Available in line with local guidance for prescribing

Respiratory			
Fluticasone fuorate, umeclidium, vilanterol (as trifenatate) 92 micrograms / 55 micrograms / 22 micrograms inhalation powder (Trelegy® Ellipta®) **SMC No 1303/18** 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	**Category 2** Available in line with local guidance for prescribing
Fluticasone propionate/ formoterol fumarate 50microgram/5microgram, 125microgram/5microgram pressurised inhalation, suspension (Flutiform k-haler®) **SMC No 2016** https://www.scottishmedicines.org.uk/media/3468/fluticasone-propionate-flutiform-k-haler-abb-final-may-2018-for-website.pdf	**Accepted for use** **Indication under review:** for the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β_2-agonist (LABA)] is appropriate: • For patients not adequately controlled with ICS as 'as required' inhaled short-acting β_2-agonist or • For patients already adequately controlled on both ICS and a LABA	**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 2** Available in line with local guidance for prescribing **Please note supplies of this in inhaler will not be available until the week commencing the 10th of September, therefore should not be prescribed until that date**
Rheumatology			
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	**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	**Category 2** Available in line with local guidance for prescribing

Rheumatology			
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	**Category 2** Available in line with local guidance for prescribing
Urology			
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	**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