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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.

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
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 Grade 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.	**13/2/17** **9/5/11**	**Yes** **Yes**
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** **Not recommended for use** **Indication under review**: Treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate **Etanercept** **Accepted for restricted use** **Indication under review**: for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. **SMC restriction**: - The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10; - The psoriasis has failed to respond to	**11/7/17** **14/5/12**	**Yes** **Yes**

		standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments; - etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. **<u>Ustekinumab</u>** **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.	**11/1/16**	**Yes**
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 a 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.	**14/5/12**	**Yes**
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**	**<u>Adalimumab</u>** **Not recommended for use** **Indication under review**: Treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate	**7/11/16**	**Yes**

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
Baricitinib 2mg and 4mg film-coated tablet (Olumiant®) **SMC No. (1265/17)** https://www.scottishmedicines.org.uk/files/advice/baricitinib_Olumiant_FINAL_August_2017_Amended_03.09.16_for_website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Baricitinib may be used as a monotherapy or in combination with methotrexate	**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 *Awaiting to be included in local pathway*
Beclometasone dipropionate/ formoterol fumarate dehydrate/ glycopyrronium 87 micrograms/ 5 micrograms/ 9 micrograms metered dose inhaler (Trimbow®) **SMC No (1274/17)** https://www.scottishmedicines.org.uk/files/advice/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.	**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
Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) **SMC No (1275/17)** https://www.scottishmedicines.org.uk/files/advice/bevacizumab_Avastin_Non_Sub_FINAL_August_2017_for_website.pdf	**Not recommended for use** **Indication under review:** In combination with caroplatin and paclitaxel for the treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) SMC No (1205/17) https://www.scottishmedicines.org.uk/files/advice/daratumumab_Darzalex_Resubmission_FINAL_Sept_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.	**Category 1** Available in line with national guidance
Etelcalcetide 2.5mg, 5mg, and 10mg solution for injection (Parsabiv®) SMC No. (1262/17) https://www.scottishmedicines.org.uk/files/advice/etelcalcetide_Parsabiv_FINAL_August_2017_amended_030917_for_website.pdf	**Not recommended for use** **Indication under review:** Treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy.	**Category 4** Not available as not recommended for use in NHS Scotland
Everolimus 0.25mg, 0.5mg and 0.75mg tablets (Certican®) SMC No (1288/17) https://www.scottishmedicines.org.uk/files/advice/everolimus_Certican_Non_Sub_FINAL_Oct_2017_for_website.pdf	**Not recommended for use** **Indication under review:** Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal transplant.	**Category 4** Not available as not recommended for use in NHS Scotland
Glecaprevir 100mg, pibrentasvir 40mg film-coated tablet (Maviret®) SMC No (1278/17) https://www.scottishmedicines.org.uk/files/advice/glecaprevir_pibrentasvir_Maviret_FINAL_Oct_2017_amended_30.10.17_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of chronic hepatitis C virus (HCV) infection in adults.	**Category 1** Available in line with national guidance
Magnesium glycerophosphate 4mmol chewable tablet (Neomag®) SMC No (1267/17) https://www.scottishmedicines.org.uk/files/advice/magnesium_glycerophosphate_Neomag_Abb_FINAL_August_2017_for_website.pdf	**Accepted for use** **Indication under review:** As an oral magnesium supplement for the treatment of patients with chronic magnesium loss or hypomagnesaemia as diagnosed by a doctor. Magnesium glycerphosphate is also indicated for adult patients with hypomagnesaemia due to the concomitant administration of loop and thiazide diuretics or other drugs which cause hypomagnesaemia.	**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
Ibrutinib 140-mg hard capsules (Imbruvica®) SMC No (1289/17) https://www.scottishmedicines.org.uk/files/advice/ibrutinib_Imbruvica_Non_Sub_FINAL_Oct_2017_for_website.pdf	**Not recommended for use** **Indication under review:** As a single agent for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (who do not have 17p deletion or TP53 mutation)	**Category 4** Not available as not recommended for use in NHS Scotland
Maraviroc 20mg/mL oral solution, 25mg, 75mg, 150mg and 300mg film-coated tablets (Celsentri®) SMC No (1282/17) https://www.scottishmedicines.org.uk/files/advice/maraviroc_Celsentri_Non_Sub_FINAL_Sept_2017_for_website.pdf	**Not recommended for use** **Indication under review:** In combination with other antiretroviral medicinal products for treatment-experienced adolescents and children of 2 years and older and weighing at least 10kg infected with only CCR5-tropic HIV-1 detectable.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Mercaptamine, 25mg and 75mg (as bitartrate), gastro-resistant hard capsules (Procysbi®) SMC No (1272/17) https://www.scottishmedicines.org.uk/files/advice/mercaptamine_Procysbi_FINAL_Oct_2017_amended_261017_for_website191217.pdf	**Not recommended for use** **Indication under review:** For the treatment of proven nephropathic cystinosis	**Category 4** Not available as not recommended for use in NHS Scotland
Midazolam (as maleate) 10mg/1mL oromucosal solution prefilled syringe (Epistatus® PFS) SMC No (1279/17) https://www.scottishmedicines.org.uk/files/advice/midazolam_Epistatus_Abbreviated_FINAL_Oct_2017_for_website.pdf	**Accepted for use** **Indication under review:** Treatment of prolonged, acute, conclusive seizures in children and adolescents aged 10 to less than 18 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 – date decision expected to be included
Nivolumab, 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No (1261/17) https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_FINAL_August_2017_for_website.pdf.	**Accepted for restricted use** **Indication under review:** As monotherapy, for the treatment of squamous cell cancer of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy.	**Category 3** Available from a specialist centre in another Health Board
Olaratumab 10mg/mL concentrate for solution for infusion (Lartruvo®) SMC No. (1273/17) https://www.scottishmedicines.org.uk/files/advice/olaratumab_Lartruvo_FINAL_Oct_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** In combination with doxorubicin for the treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin.	**Category 3** Available from a specialist centre in another Health Board
Opicapone 50mg hard capsules (Ongentys®) SMC No (1281/17) https://www.scottishmedicines.org.uk/files/advice/opicapone_Ongentys_Non_Sub_FINAL_Sept_2017_for_website.pdf	**Not recommended for use** **Indication under review:** Adjunctive therapy to preperations of levodopa/ DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.	**Category 4** Not available as not recommended for use in NHS Scotland
Pegvisomant 10mg, 15mg, 20mg, 25mg and 30mg powder and solvent for solution for injection (Somavert®) SMC No. (158/05) https://www.scottishmedicines.org.uk/files/advice/pegvisomant__Somavert__2nd_Resub_FINAL_Oct_2017_for_website_amended061217.pdf	**Accepted for restricted use** **Indication under review:** Treatment of adult patients with acromegaly who have had an inadequate response to surgery and / or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise IGF-1 [insulin-like growth factor 1] concentrations or was not 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 – date decision expected to be included
Raltegravir 600mg film-coated tablets (Isentress®) SMC No. (1280/17) https://www.scottishmedicines.org.uk/files/advice/raltegravir_600mg_Isentress_Abbreviated	**Accepted for restricted use** **Indication under review:** in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults and paediatric patients weighing at least 40kg.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
_FINAL_Oct_2017_for_website.pdf		
Roflumilast, 500 microgram, film coated tablet (Daxas®) **SMC No. (635/10)** https://www.scottishmedicines.org.uk/files/advice/roflumilast_Daxas_Resubmission_FINAL_August_2017_for_website.pdf	**Not recommended for use** **Indication under review:** for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in one second [FEV_1]) post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.	**Category 4** Not available as not recommended for use in NHS Scotland
Rolapitant (as hydrochloride monohydrate) 90mg film-coated tablets (Varuby®) **SMC No. (1266/17)** https://www.scottishmedicines.org.uk/files/advice/rolapitant_Varuby_FINAL_August_2017_amended_030917_for_website.pdf	**Accepted for restricted use** **Indication under review:** Prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Rolapitant is given as part of combination therapy.	**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
Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) **SMC No (1271/17)** https://www.scottishmedicines.org.uk/files/advice/sofosbuvir_velpatasvir_Epclusa_FINAL_Sept_2017_05.10.17_amended_for_website.pdf	**Accepted for restricted use** **Indication under review:** Treatment of chronic hepatitis C virus (HCV) infection in adults.	**Category 1** Available in line with national guidance
Stiripentol 250mg and 500mg hard capsule, 250mg and 500mg powder for oral suspension in sachet (Diacomit®) **SMC No. (524/08)** https://www.scottishmedicines.org.uk/files/advice/stiripentol_Diacomit_Resubmission_FINAL_August_2017_for_website.pdf	**Accepted for use** **Indication under review:** in conjunction with clobazam and valporate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI; Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valporate.	**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

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL vial for paediatric use SMC No. (1243/17) https://www.scottishmedicines.org.uk/files/advice/adalimumab_Humira_Abbreviated_FINAL_May_2017_for_website.pdf	**Accepted for use** **Indication under review:** treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS 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 – decision expected by 28/9/17	**Category 2** Available in line with local guidance for prescribing
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** 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/files/advice/ciprofloxacin-dexamethasone_Cilodex_Abbreviated_FINAL_June_2017_for_website.pdf	Treatment of the following infections in adults and children: Acute otitis media in patients with tympanostomy 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 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
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	Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria 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	**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/files/advice/dequalinium_Fluomizin_FINAL_Oct_2016_Amended_31.10.16_for_website.pdf	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 – decision expected by 28/9/17	**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
Evolocumab 140mg solution for injection in pre-filled pen (Repatha® Sureclick) or pre-filled syringe (Repatha® PFS) SMC No. (1148/16) https://www.scottishmedicines.org.uk/files/advice/evolocumab__Repatha__Resubmission_FINAL_Jan_2017_for_website.pdf	**Accepted for restricted use** **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. **SMC restriction:** for specialist use only, when administered at a dose of 140mg every two weeks, 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	**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
Glycopyrronium 320 micrograms/mL (glycopyrronium bromide 400 micrograms/mL) oral solution (Sialanar®) SMC No. (1254/17) https://www.scottishmedicines.org.uk/files/advice/glycopyrronium_bromide_Sialanar_Abbreviated_FINAL_June_2017_for_website.pdf	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 – decision expected by 28/9/17	**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 *Classified as Category 5 as no response back from clinician within the 3 month timescale*
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