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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 445 – Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs**	**Refer to NICE documentation for full guidance** **www.nice.org.uk/guidance/445**	**certolizumab pegol (Cimzia®):** is accepted for restricted use within NHS Scotland. **Indication under review**: in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. **SMC restriction**: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination. **secukinumab (Cosentyx®)** is accepted for restricted use within NHS Scotland. **Indication under review:** alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. SMC restriction: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.	**7/7/14** **8/8/16**	**Yes** **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 – date decision expected to be included

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

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®) SMC No. (1260/17) https://www.scottishmedicines.org.uk/files/advice/5-aminolaevulinic_acid_Ameluz_FINAL_July_2017_for_website.pdf	**Not recommended** **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 4** Not recommended for use in NHS Scotland
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
Aprepitant, 80mg, 125mg hard capsules and 125mg powder for oral suspension (Emend®) SMC No (1241/17) https://www.scottishmedicines.org.uk/files/advice/aprepitant_Emend_FINAL_May_2017_Amended_060617_for_website.pdf1/17)	**Accepted for use** **Indication under review:** As part of combination therapy, for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in infants, toddlers and children from the age of six months to less than 12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules). Aprepitant is given as part of combination therapy.	**Category 1** - Available in line with national guidance
Budesonide/formoterol 100 micrograms/6 micrograms and 200 micrograms/6 micrograms inhalation powder (Symbicort® SMART®) SMC No. (1244/17) https://www.scottishmedicines.org.uk/files/advice/budesonide-formoterol_Symbicort_SMART_Abb_FINAL_May_2017_for_website.pdf	**Accepted for use** **Indication under review:** the regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β_2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" short-acting β_2 adrenoceptoragonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists.	**Category 1 -** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Buprenorphine 2mg, 8mg oral lyophilisate (Espranor®) SMC No (1245/17) https://www.scottishmedicines.org.uk/files/advice/buprenorphine_oral_lyophilsate_Espranor_Abb_-_amended_advice_270717.pdf	**Accepted for restricted use** **Indication under review:** Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction **SMC restriction:** to patients in whom methadone is not suitable.	**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
Cabozantinib 20mg, 40mg and 60mg film-coated tablets (Cabometyx®) SMC No. (1234/17) https://www.scottishmedicines.org.uk/files/advice/cabozantinib_Cabometyx_FINAL_May_2017_for_website.pdf	**Accepted for use** **Indication under review:** For the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.	**Category 1** - Available in line with national guidance
Canakinumab 150mg powder for solution for injection (Ilaris®) SMC No (1268/17) https://www.scottishmedicines.org.uk/files/advice/canankinumab_Ilaris_Non_Sub_FINAL_July_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older: • tumour necrosis factor receptor associated periodic syndrome • hyperimmunoglobulin D syndrome / mevalonate kinase deficiency • Familial Mediterranean Fever	**Category 4** Not recommended for use in NHS Scotland
Carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®). SMC No. (1242/17) https://www.scottishmedicines.org.uk/files/advice/carfilzomib_Kyprolis_FINAL_July_2017_for_website.pdf	**Accepted for use** **Indication Under review:** In combination with dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	**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	**Accepted for restricted use** **Indication under review:** 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 – decision expected by 28/9/17
Deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®) SMC No (1246/17) https://www.scottishmedicines.org.uk/files/advice/deferasirox_Exjade_Abbreviated_FINAL_May_2017_Amended_050617_for_website.pdf	**Accepted for restricted use** **Indication under review** Treatment of chronic iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups: • in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) aged 2 to 5 years, • in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7mL/kg/month of packed red blood cells) aged 2 years and older, • in adult and paediatric patients with other anaemias aged 2 years and older. **SMC restriction:** deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07).	**Category 1 -** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
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.	**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
Dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) SMC No (1253/17) https://www.scottishmedicines.org.uk/files/advice/dolutegravir_Tivicay_Abbreviated_FINAL_June_2017_for_website.pdf	**Accepted for use** **Indication under review:** in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged >6 to 12 years of age. **Product Update**	**Category 1** - Available in line with national guidance
Emtricitabine / tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No (1263/17) https://www.scottishmedicines.org.uk/files/advice/emtricitabine-tenofovir_disoproxil_Truvada_Non_Submission_FINAL_June_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of HIV-1 infected adolescents aged 12 to <18 years with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line agents.	**Category 4** Not recommended for use in NHS Scotland
Follitropin delta 12 micrograms, 36 micrograms and 72 micrograms solution for injection (Rekovelle®) SMC No: (1269/17) https://www.scottishmedicines.org.uk/files/advice/follitropin_Rekovelle_Non_Sub_FINAL_July_2017_for_website.pdf	**Not recommended** **Indication under review:** Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies such as an in vitro fertilisation or intracytoplasmic sperm injection cycle.	**Category 4** Not recommended for use in NHS Scotland
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	**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 – decision expected by 28/9/17
Ibrutinib (Imbruvica®) 140mg hard capsules SMC No (1258/17) https://www.scottishmedicines.org.uk/files/advice/ibrutinib_Imbruvica_Non_Sub_FINAL_May_2017_for_website.pdf	**Not recommended** **Indication under review:** In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy.	**Category 4** Not recommended for use in NHS Scotland
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No (1240/17) https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_cHL_FINAL_June_2017_for_website.pdf	**Accepted for use** **Indication under review:** the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.	**Category 1** - Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No. (1188/16) https://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_RESUBMISSION_FINAL_May_2017_for_website.pdf	**Accepted for use** **Indication under review:** As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults.	**Category 1** - Available in line with national guidance
Obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva®) SMC No (1232/17) https://www.scottishmedicines.org.uk/files/advice/obeticholic_acid_Ocaliva_FINAL_May_2017_Amended_170517_for_website.pdf	**Accepted for use** **Indication under review:** primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid.therapy.	**Category 1** - Available in line with national guidance
Pembrolizumab 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion (Keytruda®) SMC No. (1239/17) https://www.scottishmedicines.org.uk/files/advice/pembrolizumab_Keytruda_FINAL_June_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** As monotherapy for the first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) with a ≥50% tumour proportion score (TPS) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) positive tumour mutations. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule.	**Category 1** - Available in line with national guidance
Pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) SMC No. (897/13) https://www.scottishmedicines.org.uk/files/advice/pertuzumab_Perjeta_2nd_Resub_FINAL_May_2017_for_website.pdf	**Not recommended** **Indication under review:** for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	**Category 4** Not recommended for use in NHS Scotland
Safinamide (Xadago®) 50mg / 100mg film-coated tablets Zambon S.p.A. SMC No (1259/17) https://www.scottishmedicines.org.uk/files/advice/safinamide_Xadago_Non_Sub_FINAL_May_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.	**Category 4** Not recommended for use in NHS Scotland
Saxagliptin 5mg / dapagliflozin 10mg film-coated tablets (Qtern®) SMC No (1255/17) https://www.scottishmedicines.org.uk/files/advice/saxagliptin-dapagliflozin_Qtern_Abbreviated_FINAL_June_2017_for_website.pdf	**Accepted for restricted use** **Indication under review:** in adults aged 18 years and older with type 2 diabetes mellitus: • to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Qtern® do not provide adequate glycaemic control, • when already being treated with the free combination of dapagliflozin and saxagliptin **SMC restriction:** for use in combination with metformin when the use of a sulphonylurea is inappropriate. **Product Update**	**Category 5** - Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
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) https://www.scottishmedicines.org.uk/files/advice/selexipag_Uptravi_FINAL_June_2017_for_website_amended_10.08.17.pdf	**Not recommended** **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.	**Category 4** Not recommended for use in NHS Scotland
Sufentanil citrate 15 micrograms sublingual tablets (Zalviso®) SMC No (1270/17) https://www.scottishmedicines.org.uk/files/advice/sufentanil_Zalviso_Non_Sub_FINAL_July_2017_for_website.pdf	**Not recommended** **Indication under review:** Management of acute moderate to severe post-operative pain in adult patients.	**Category 4** Not recommended for use in NHS Scotland
Trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) SMC No (1264/17) https://www.scottishmedicines.org.uk/files/advice/trametinib_Mekinist_Non_Submission_FINAL_June_2017_for_website.pdf	**Not recommended** **Indication under review:** in combination with dabrafenib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation.	**Category 4** Not recommended for use in NHS Scotland
Ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (Stelara®) SMC No. (1250/17) https://www.scottishmedicines.org.uk/files/advice/ustekinumab_Stelara_FINAL_June_2017_for_website.pdf	**Accepted for use** **Indication under review:** for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist or have medical contraindications to such therapies.	**Category 1** - Available in line with national guidance
Venetoclax, 10mg, 50mg and 100mg film-coated tablets (Venclyxto®) SMC No. (1249/17) https://www.scottishmedicines.org.uk/files/advice/talimogene_laherparepvec_Imlygic_Non_Sub_FINAL_April_2017_for_website.pdf	**Accepted for use** **Indication under review** as monotherapy for the treatment of chronic lymphocytic leukaemia (CLL): • in the presence of 17p deletion or *TP53* mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor. • in the absence of 17p deletion or *TP53* mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.	**Category 1** - Available in line with national guidance

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®) SMC No 1158/16 https://www.scottishmedicines.org.uk/files/advice/vortioxetine_Brintellix_FINAL_June_2016_for_website.pdf	**Accepted for restricted use** **Indication under review**: the treatment of major depressive episodes in adults. **SMC restriction**: patients who have experienced an inadequate response (either due to lack of adequate efficacy and/or safety concerns/intolerability) to two or more previous antidepressants	**Category 6** - Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**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
Daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®) SMC No 1216/17 https://www.scottishmedicines.org.uk/files/advice/daclizumab_Zinbryta_FINAL_March_2017_for_website.pdf17	**Accepted for restricted use** **Indication under review**: In adult patients for the treatment of relapsing forms of multiple sclerosis. **Restriction: for use** • in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or • in patients with RRMS with an inadequate response to disease modifying 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	**Category 1** - Available in line with national guidance
Emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No 1225/17 https://www.scottishmedicines.org.uk/files/advice/emtricitabine_tenofovir_disoproxil_Truvada_FINAL_March_2017_for_website.pdf	**Accepted for use** **Indication under review**: In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk	**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
Naloxegol 12.5mg and 25mg film-coated tablets (Moventig®) SMC No 1106/15 https://www.scottishmedicines.org.uk/files/advice/naloxegol__Moventig__FINAL_Nov_2015_for_website.pdf	**Accepted for use** **Indication under review:** the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s).	**Category 6** - 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