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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) and Peer Approved Clinical System (PACS) processes 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 these policies 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
http://staffnet.fv.scot.nhs.uk/a-z/pharmacy/

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): NICE MTAs are no longer assessed on a national basis for applicability to Scotland by Healthcare Improvement Scotland, however, as ADTCs may consider NICE MTA advice for applicability in their Board area, National Procurement provide ADTCs with up to date pricing information for medicines that are subject to a NICE MTA.

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 – 535 Lenvatinib and Sorafenib for treating differentiated thyroid cancer after radioactive iodine	https://www.nice.org.uk/guidance/ta535	**Lenvatnib** **Accepted for use** **Indication under review:** treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). **Sorafenib** **Accepted for use** **Indication under review**: treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.	**10/10/16** **13/7/15**	**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

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
Blood & Nutrition		
Glycerol phenylbutyrate 1.1g/mL oral liquid (Ravicti®) **SMC No 1342/18** https://www.scottishmedicines.org.uk/media/3649/glycerol-phenylbutyrate-ravict-final-july-2018-for-website.pdf	**Accepted for use** **Indication under review:** or use as adjunctive therapy for chronic management of adult and paediatric patients ≥2 months of age with urea cycle disorders (UCDs) including deficiencies of carbamoyl phosphate synthase I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Glycerol phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, protein-free calorie supplements).	**Category 3** Available from a specialist centre in another NHS Board
Patiromer (as patiromer sorbitex calcium) 8.4g and 16.8g powder for oral suspension (Veltassa®) **SMC No 2084** https://www.scottishmedicines.org.uk/media/3651/patiromer-sorbitex-calcium-veltassa-final-july-2018-for-website.pdf	**Not recommended** **Indication under review:** for the treatment of hyperkalaemia in adults.	**Category 4** Not available as not recommended for use in NHS Scotland
Sapropterin dihydrochloride, 100mg, soluble tablets (Kuvan®) **SMC No 558/09** https://www.scottishmedicines.org.uk/media/3652/sapropterin-kuvan-final-july-2018-for-website.pdf	**Not recommended** **Indication under review:** the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment.	**Category 4** Not available as not recommended for use in NHS Scotland
Dermatology		
Dupilumab 300mg solution for injection in pre-filled syringe (Dupixent®) **SMC No 2011** https://www.scottishmedicines.org.uk/media/3690/dupilumab-dupixent-final-august-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. **SMC restriction:** patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
HIV		
Bictegravir 50mg / emtricitabine 200mg / tenofovir alafenamide 25mg film-coated tablet (Biktarvy®) **SMC No 745/11** https://www.scottishmedicines.org.uk/media/3687/bictegravir-biktarvy-final-august-2018-amended-310818-for-website.pdf	**Accepted for use** **Indication under review:** Treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Dolutegravir 50mg / rilpivirine 25mg film-coated tablets (Juluca®) **SMC No 2091** https://www.scottishmedicines.org.uk/media/3689/dolutegravir-rilpivirine-juluca-final-august-2018-amended-310818-for-website.pdf	**Accepted for use** **Indication under review:** The treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase inhibitor.	**Category 1** Available in line with national guidance
Immunosupression		
Sirolimus 0.5mg, 1mg and 2mg coated tablets and 1mg/ml oral solution (Rapamune®) **SMC No 2126** https://www.scottishmedicines.org.uk/media/3759/sirolimus-rapamune-non-sub-final-sept-2018-for-website.pdf	**Not recommended** **Indication under review:** treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function	**Category 4** Not available as not recommended for use in NHS Scotland
Oncology		
Alectinib 150mg hard capsules (Alecensa®) **SMC No 2012** https://www.scottishmedicines.org.uk/media/3645/alectinib-hydrochloride-alecensa-final-july-2018-for-website.pdf	**Accepted for use** **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 (NSCLC)	**Category 1** Available in line with national guidance
Bosutinib 100mg, 400mg and 500mg film-coated tablets (Bosulif®) **SMC No 2109** https://www.scottishmedicines.org.uk/media/3646/bosutinib-bosulif-non-sub-final-july-2018-for-website.pdf	**Not recommended** **Indication under review:** Treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukaemia.	**Category 4** Not available as not recommended for use in NHS Scotland
Cabozantinib, 20mg, 40mg, and 60mg film-coated tablets (Cabometyx®) **SMC No 2095** https://www.scottishmedicines.org.uk/media/1395/cabozantinib_cabometyx_final_may_2017_for_website.pdf	**Not recommended** **Indication under review:** advanced renal cell carcinoma (RCC) in treatment-naïve adults with intermediate or poor risk.	**Category 4** Not available as not recommended for use in NHS Scotland
Gemtuzumab ozogamicin 5mg powder for concentrate for solution for infusion (Mylotarg®) **SMC No 2089** https://www.scottishmedicines.org.uk/media/3765/gemtuzumab-ozogamicin-mylotarg-final-september-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** For combination therapy with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL). **SMC restriction:** use in patients with a favourable, intermediate or unknown cytogenetic profile.	**Category 1** Available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) **SMC No 2094** https://www.scottishmedicines.org.uk/media/3767/ipilimumab-yervoy-abb-final-sept-2018-for-website.pdf	**Accepted for use** **Indication under review:** as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adolescents 12 years of age and older.	**Category 3** Available from a specialist centre in another NHS Board
Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules (Revlimid®) **SMC No 2125** https://www.scottishmedicines.org.uk/media/3760/lenalidomide-revlimid-non-sub-final-sept-2018-for-website.pdf	**Not recommended** **Indication under review:** As monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.	**Category 4** Not available as not recommended for use in NHS Scotland
Niraparib tosylate monohydrate 100mg hard capsules (Zejula®) **SMC No 1341/18** https://www.scottishmedicines.org.uk/media/3650/niraparib-tosylate-monohydrate-zejula-final-july-2018-amended-240718-for-website.pdf	**Accepted for restricted use** **Indication under review:** As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. **SMC restriction:** to patients who do not have a germline *BRCA* mutation.	**Category 3** Available from a specialist centre in another NHS Board
Obinutuzumab, 1,000mg, concentrate for solution for infusion (Gazyvaro®) **SMC No 2015** https://www.scottishmedicines.org.uk/media/3691/obinutuzumab-gazyvaro-resubmission-final-august-2018-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 available as not recommended for use in NHS Scotland
Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) **SMC No 1339/18** https://www.scottishmedicines.org.uk/media/3692/pembrolizumab-keytruda-final-august-2018-for-website.pdf	**Not recommended** **Indication under review:** as monotherapy, for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS)≥10.	**Category 4** Not available as not recommended for use in NHS Scotland
Opthalmology		
Cenegermin 20mg/ml eye drops, solution (Oxervate®) **SMC No 2124** https://www.scottishmedicines.org.uk/media/1395/cabozantinib_cabometyx_final_may_2017_for_website.pdf	**Not recommended** **Indication under review:** Treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults.	**Category 4** Not available as not recommended for use in NHS Scotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Orthopaedics / Rheumatology		
Denosumab 60mg solution for injection in pre-filled syringe (Prolia ®) **SMC No 2117** https://www.scottishmedicines.org.uk/media/3688/denosumab-prolia-non-sub-final-august-2018-for-website.pdf	**Not recommended** **Indication under review:** Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.	**Category 4** Not available as not recommended for use in NHS Scotland
Paediatrics		
Anakinra 100mg/0.67mL solution for injection in pre-filled syringe (Kineret®) **SMC No 2104** https://www.scottishmedicines.org.uk/medicines-advice/anakinra-kineret-fullsubmission-smc2104/	**Accepted for use** **Indication under review**: in adults, adolescents, children and infants aged eight months and older with a body weight of 10kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs	**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
Hydrocortisone 0.5mg, 1mg, 2mg and 5mg granules in capsules for opening (Alkindi®) **SMC No 2088** https://www.scottishmedicines.org.uk/media/3758/hydrocortisone-granules-alkindi-final-september-2018-for-website.pdf	Accepted for restricted use **Indication under review:** replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <18 years old). **SMC restriction:** for the first-line treatment of infants and young children with adrenal insufficiency aged from birth to less than six years of age for whom hydrocortisone must otherwise be individually prepared by manipulation such as by compounding (or crushing) or by production of special solutions in order to produce age-appropriate doses, or hydrocortisone given as off-label buccal tablets.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Respiratory		
Conestat alfa 2,100 units powder (and solvent) for solution for injection (Ruconest®) **SMC No 745/11** https://www.scottishmedicines.org.uk/media/3647/conestat-alfa-ruconest-final-20180808-for-website.pdf	**Accepted for restricted use** **Indication under review:** For treatment of acute angioedema attacks in adults and adolescents with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.	**Category 3** Available from a specialist centre in another NHS Board
Rheumatology		
Ixekizumab 80mg solution for injection in pre-filles syringe or pen (Taltz®) **SMC No 2097** https://www.scottishmedicines.org.uk/media/3763/ixekizumab-taltz-final-sept-2018-amended-230918-for-website.pdf	Accepted for restricted use **Indication under review:** ixekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. **SMC restriction:** patients whose disease has not responded adequately to at least two conventional DMARDs given either alone or in combination, and who have had an inadequate response to a tumour necrosis factor (TNF)-inhibitor.	**Category 2** Available in line with local guidance for prescribing

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Tocilizumab, 162mg solution for injection in pre-filled syringe and pre-filled pen (RoActemra®) **SMC No 2014** https://www.scottishmedicines.org.uk/media/3693/tocilizumab-roactemra-final-august-2018-for-website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of Giant Cell Arteritis (GCA) in adult patients **SMC restriction:** treatment with tocilizumab is subject to a 12 month clinical stopping rule.	**Category 6** Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Anakinra 100mg/0.67mL solution for injection in pre-filled syringe (Kineret®) **SMC No 2104** https://www.scottishmedicines.org.uk/medicines-advice/anakinra-kineret-fullsubmission-smc2104/	**Accepted for use** **Indication under review**: in adults, adolescents, children and infants aged eight months and older with a body weight of 10kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs	**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

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