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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 not been recommended 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 are 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 Quality Improvement Website on the following link:
https://guidelines.staffnet.fv.scot.nhs.uk/pharmacy-and-precribing/

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.

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
Dermatology		
Dupilumab 200mg and 300mg solution for injection in pre-filled syringe (Dupixent®) **SMC Number 2232** https://www.scottishmedicines.org.uk/media/4976/dupilumab-dupixent-abbreviated-final-december-2019-for-website.pdf	**Accepted for restricted use** **Indication under review:** the treatment of moderate-to-severe atopic dermatitis in adolescents (≥12 to <18 years) 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 2** – available in line with local guidance for prescribing
Imiquimod 3.75% cream (Zyclara®) **SMC No 2211** https://www.scottishmedicines.org.uk/media/4884/imiquimod-zyclara-final-october-2019-for-website.pdf	**Accepted for restricted use** **Indication under review:** for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate. **SMC restriction:** for the treatment of large field actinic keratosis (>25cm^2).	**Category 1** - available in line with national guidance
Gastroenterology		
Teduglutide 5mg vial of powder and solvent for solution for injection (Revestive®) **SMC Number 2225** https://www.scottishmedicines.org.uk/medicines-advice/teduglutide-revestive-fullsubmission-113916/	**Accepted for use** **Indication under review:** for the treatment of patients age 1 year and above with short bowel syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.	**Category 6 –** not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Haematology		
Lusutrombopag 3mg film-coated tablets (Mulpleo®) **SMC Number 2227** https://www.scottishmedicines.org.uk/media/4939/lusutrombopag-mulpleo-final-november-2019-for-website.pdf	**Accepted for use** **Indication under review:** for the treatment of severe thrombocytopenia in adult patients with chronic liver disease undergoing invasive procedures.	**Category 6 –** not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts
Ruxolitinib phosphate 5mg, 10mg, 15mg, 20mg tablets (Jakavi®) **SMC Number 2213** https://www.scottishmedicines.org.uk/media/4942/ruxolitinib-jalkavi-final-november-2019-for-website.pdf	**Accepted for use** **Indication under review:** The treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea (hydroxycarbamide).	**Category 1** - available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Neurology		
Fremanezumab 225mg solution for injection in pre-filled syringe (Ajovy®) **SMC Number 2226** https://www.scottishmedicines.org.uk/media/4977/fremanezumab-ajovy-final-december-2019-amended-191219-for-website.pdf	**Accepted for restricted use** **Indication under review:** For prophylaxis of migraine in adults who have at least four migraine days per month. **SMC restriction:** for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.	**Category 5 –** not routinely available as local clinical experts do not wish to add medicines to the formulary at this time or there is local preference for an alternative
Ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®) **SMC Number 2223** https://www.scottishmedicines.org.uk/media/4978/ocrelizumab-ocrevus-final-december-2019-for-website.pdf	**Accepted for use** **Indication under review:** for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity.	**Category 1** - available in line with national guidance
Clostridium botulinum neurotoxin type A 50, 100, and 200 units powder for solution for injection (Xeomin®) **SMC No 2212** https://www.scottishmedicines.org.uk/media/4880/clostridium-botulinum-neurotoxin-type-a-xeomin-final-october-2019-for-website.pdf	**Accepted for use** **Indication under review:** for the symptomatic treatment of chronic sialorrhoea due to neurological disorders in adults.	**Category 1** - available in line with national guidance
Oncology		
Abiraterone acetate 500mg film-coated tablets (Zytiga®) **SMC Number 2215** https://www.scottishmedicines.org.uk/media/4979/abiraterone-zytiga-final-december-2019-amended-181219-for-website.pdf	**Accepted for use** **Indication under review:** abiraterone acetate with prednisone or prednisolone for the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer in adult men in combination with androgen deprivation therapy.	**Category 1 –** available in line with national guidance
Brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®) **SMC Number 2229** https://www.scottishmedicines.org.uk/media/4980/brentuximab-vedotin-adcetris-final-december-2019-for-website.pdf	**Accepted for restricted use** **Indication under review:** The treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. **SMC restriction:** for the treatment of patients with advanced CTCL, defined as mycosis fungoides stage IIB and above, primary cutaneous anaplastic large cell lymphoma or Sézary Syndrome.	**Category 1 –** available in line with national guidance
Cemiplimab 350mg concentrate for solution for infusion (Libtayo®) **SMC Number 2216** https://www.scottishmedicines.org.uk/media/5057/cemiplimab-libtayo-final-jan-2020-for-website.pdf	**Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment.** **Indication under review:** As monotherapy for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation	**Category 1 –** available in line with national guidance
Encorafenib 50mg and 75mg hard capsules (Braftovi®) **SMC Number 2238** https://www.scottishmedicines.org.uk/media/5051/encorafenib-braftovi-final-jan-2020-for-website.pdf	**Accepted for use** **Indication under review:** In combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.	**Category 1 –** available in line with national guidance
Olaparib 100mg and 150mg film-coated tablets (Lynparza®) **SMC Number 2209** https://www.scottishmedicines.org.uk/media/4940/olaparib-	**Accepted for use** **Indication under review:** for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy	**Category 1 –** available in line with national guidance

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
lynparza-final-november-2019-for-website.pdf		
Plerixafor 20mg/mL solution for injection (Mozobil®) **SMC Number 2249** https://www.scottishmedicines.org.uk/media/5052/plerixafor-mozobil-abbreviated-final-jan-2020-for-website.pdf	**Accepted for use** **Indication under review:** in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged 1 year to <18 years with lymphoma or solid malignant tumours, either: - pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilisation with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or - who previously failed to collect sufficient haematopoietic stem cells.	**Category 1 –** available in line with national guidance
Ophthalmology		
Voretigene neparvovec 5×10^{12} vector genomes/mL concentrate and solvent for solution for injection (Luxturna®) **SMC Number 2228** **Through the Ultra Orphan Framework** https://www.scottishmedicines.org.uk/media/5066/umar-voretigene-luxturna-final-november-2019-for-website.pdf	**Indication under review:** For the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.	**Category 1 –** available in line with national guidance Not included on formulary due to low patient numbers
Paediatrics		
Burosumab 10mg, 20mg, and 30mg solution for injection (Crysvita®) **SMC Number 2240** https://www.scottishmedicines.org.uk/media/5067/umar-burosumab-crysvita-final-jan-2020-amended-150120-for-website.pdf	The Scottish Medicines Consortium (SMC) has completed its initial assessment of the evidence for the above product using the ultra-orphan framework: **Indication under review:** Treatment of X-linked hypophosphataemia with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons.	**Category 1 –** available in line with national guidance Not included on formulary due to low patient numbers
Public Health		
Zanamivir 10mg/mL solution for infusion (Dectova®) **SMC Number 2204** https://www.scottishmedicines.org.uk/media/4944/zanamivir-dectova-abbreviated-final-august-2019-for-website.pdf	**Accepted for use** **Indication under review:** Treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥ 6 months) when: • the patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or • other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient.	**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		
Lanadelumab 300mg solution for injection (Takhzyro®) **SMC Number 2206** https://www.scottishmedicines.org.uk/media/4947/lanadelumab-takhzyro-final-november-2019-for-website.pdf	**Accepted for restricted use** **Indication under review:** For the routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older. **SMC restriction:** patients with HAE type I or II, who would otherwise be considered for long-term prophylaxis treatment with C1-esterase inhibitor.	**Category 3** - available from a specialist centre in another Health Board

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Not Recommended		
Apalutamide 60mg film-coated tablets (Erleada®) **SMC Number 2268** https://www.scottishmedicines.org.uk/media/5056/apalutamide-erleada-non-sub-final-jan-2020-for-website.pdf	**Indication under review:** In adult men for the treatment of non-metastatic castration-resistant prostate cancer (NM-CRPC) who are at high risk of developing metastatic disease.	**Category 4 –** not available as not recommended for use in NHSScotland
Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) **SMC Number 2254** https://www.scottishmedicines.org.uk/media/4945/atezolizumab-tecentriq-non-sub-final-november-2019-for-website.pdf	**Indication under review:** In combination with nab-paclitaxel and carboplatin for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR mutant or ALK-positive NSCLC.	**Category 4 –** not available as not recommended for use in NHSScotland
Ceftolozane / tazobactam 1g/0.5g powder for concentrate for solution for infusion (Zerbaxa®) **SMC Number 2256** https://www.scottishmedicines.org.uk/media/4946/ceftolozane-tazobactam-zerbaxa-non-sub-final-november-2019-for-website.pdf	**Indication under review:** In adults for the treatment of hospital acquired pneumonia, including ventilator-associated pneumonia.	**Category 4 –** not available as not recommended for use in NHSScotland
Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) **SMC Number 2269**	**Indication under review:** In combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.	**Category 4 –** not available as not recommended for use in NHSScotland
Prasterone 6.5mg pessary (Intrarosa®) **SMC Number 2255** https://www.scottishmedicines.org.uk/media/4941/prasterone-intrarosa-non-sub-final-november-2019-for-website.pdf	**Indication under review:** Treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms.	**Category 4 –** not available as not recommended for use in NHSScotland
Ranibizumab 10mg/mL solution for injection / 10mg/mL solution for injection in pre-filled syringe (Lucentis®) **SMC Number 2270** https://www.scottishmedicines.org.uk/media/5053/ranibizumab-lucentis-non-sub-final-jan-2020-for-website.pdf	**Indication under review:** treatment of proliferative diabetic retinopathy in adults.	**Category 4 –** not available as not recommended for use in NHSScotland
Sodium zirconium cyclosilicate 5g and 10g powder for oral suspension (Lokelma®) **SMC Number 2233** https://www.scottishmedicines.org.uk/media/5065/sodium-zirconium-cyclosilicate-lokelma-final-jan-2020-amended-060220-for-website.pdf	**Indication under review:** treatment of hyperkalaemia in adult patients.	**Category 4 –** not available as not recommended for use in NHSScotland

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Trabectedin 0.25mg and 1mg powder for concentrate for solution for infusion (Yondelis®) **SMC Number 2210** https://www.scottishmedicines.org.uk/media/4943/trabectedin-yondelis-final-november-2019-amended-251119-for-website.pdf	**Indication under review:** treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.	**Category 4 –** not available as not recommended for use in NHSScotland

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position
Ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®) **SMC Number 2121** https://www.scottishmedicines.org.uk/media/3966/ocrelizumab-ocrevus-rrms-resub-final-nov-2018-amended-051218-for-website.pdf	Accepted for restricted **Indication under review:** The treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. **SMC restriction:** Treatment of relapsing remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features who are contra-indicated or otherwise unsuitable for alemtuzumab.	**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
Cladribine 10mg tablet (Mavenclad®) **SMC Number 1300/18** https://www.scottishmedicines.org.uk/media/3097/cladribine_mavenclad_final_jan_2018_amended_070218_for_website.pdf	**Accepted for restricted use** **Indication under review:** treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features. **SMC restriction:** • Patients with rapidly evolving severe relapsing-remitting MS: patients with two or more relapses in the prior year whether on treatment or not, and at least one T1 gadolinium-enhancing lesion. • Patients with sub-optimal therapy relapsing-remitting MS: patients with one or more relapses in the previous year while on disease modifying therapy, and at least one T1 gadolinium-enhancing lesion or nine T2 lesions.	**Category 6 –** not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	**Category 2** – available in line with local guidance
Risankizumab 75mg solution for injection in pre-filled syringe (Skyrizi®) **SMC Number 2196** https://www.scottishmedicines.org.uk/media/3097/cladribine_mavenclad_final_jan_2018_amended_070218_for_website.pdf	**Accepted for restricted use** **Indication under review:** for the 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	**Category 2** – available in line with local guidance
Pentosan polysulfate sodium 100mg hard capsules (Elmiron®) **SMC No 2194** https://www.scottishmedicines.org.uk/media/4886/pentosan-elmiron-final-october-2019-for-website.pdf	**Accepted for use** **Indication under review:** for the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.	**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

Formulary Changes

Formulary section	Current Product	Changed to	Comments
1. Gastro-intestinal System	Co-magaldrox	Added in Brand of choice Mucogel	
	Dicycloverine	Removed	No longer on formulary preferred formulary 1st line choice is mebeverine
	Linaclotide		Specialist initiation in line with SMC recommendation
	Ursodeoxycholic acid	Preferred formulation is 250mg capsules	More cost effective to prescribe as capsules rather than tablets
4.4.4 Antimigraine Drugs	Pizotifen	Removed	Preferred treatment for migraine prophylaxis are propranolol, amitryptyline, candesartan or topiramate
	Triptans		Preferred formulary choice triptans are sumatriptan, rizatriptan and frovatriptan
4.7 Pain	Duloxetine		Can now be initiated in primary care for patients with neuropathic pain. For further information refer to the guideline Treatment for Neuropathic Pain
6 Endocrine **6.4** Sex Hormones	The HRT section has been updated to highlight preferred formulary choices, combination products and oestrogen products with 1st and 2nd line choices for tablets and patches. The preferred formulary choices reflect current availability and cost		

The Forth Valley Formulary can be accessed from the staff net homepage under quick links - click on clinical resources then FV formulary or access via the link below

Forth Valley Formulary « StaffNet

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