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ADTC Newsletter

New Drugs and Therapeutic Advances



Outlined 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-prescribing/>

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 Therapeutic Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in the future. For full **SMC advice** on specific drugs please refer to the SMC website www.scottishmedicines.org

Category Classification

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

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Cardiology (Renal)			
<p>Sodium zirconium cyclosilicate 5g and 10g powder for oral suspension (Lokelma®) SMC Number: 2288 https://www.scottishmedicines.org.uk/media/5371/sodium-zirconium-cyclosilicate-lokelma-final-august-2020docx-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: treatment of hyperkalaemia in adult patients. SMC restriction: patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia)</p>	<p>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 local preference for alternative medicines.</p>	<p>Not applicable</p>
Endocrinology			
<p>Semaglutide 3mg, 7mg and 14mg tablets (Rybelsus®) SMC Number: 2287 https://www.scottishmedicines.org.uk/media/5361/semaglutide-rybelsus-abbreviated-final-august-2020docx-for-website.pdf</p>	<p>Indication under review: for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise</p> <ul style="list-style-type: none"> As monotherapy when metformin is considered inappropriate due to intolerance or contraindications In combination with other medicinal products for the treatment of diabetes. <p>SMC restriction: In addition to other oral anti-diabetic medicines, or as an add-on to basal insulin, as an alternative glucagon-like peptide-1 receptor agonist option</p>	<p>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 local preference for alternative medicines.</p>	<p>Not applicable</p>
Gastroenterology			
<p>Vedolizumab 108mg solution for subcutaneous injection in pre-filled syringe or pre-filled pen (Entyvio®) SMC Number: 2276 https://www.scottishmedicines.org.uk/media/5277/vedolizumab-entyvio-uc-abbreviated-final-july-2020-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: the treatment of adult patients with moderately to severely active ulcerative colitis 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.</p>	<p>Category 1 – available in line with national guidance</p>	<p>Acute Services</p>
<p>Vedolizumab 108mg solution for subcutaneous injection in pre-filled syringe or pre-filled pen (Entyvio®) SMC Number: 2277 https://www.scottishmedicines.org.uk/media/5276/vedolizumab-entyvio-cd-abbreviated-final-july-2020-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. 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. SMC restriction: 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 a TNFα antagonist.</p>	<p>Category 1 – available in line with national guidance</p>	<p>Acute Services</p>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Gastroenterology			
Budesonide 1mg orodispersible tablets (Jorveza®) SMC Number: 2158 https://www.scottishmedicines.org.uk/media/5460/budesonide-jorveza-final-september-2020-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: Treatment of eosinophilic oesophagitis (EoE) in adults (older than 18 years of age). SMC restriction: For patients unsuccessfully treated with proton pump inhibitors.	Category 6 – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.	Not Applicable
Haematology			
Andexanet alfa 200 mg powder for solution for infusion (Ondexxya®) SMC Number: 2273 https://www.scottishmedicines.org.uk/media/5372/andexanet-alfa-ondexxya-final-august-2020-amended-180820-for-website.pdf	Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.	Category 1 – available in line with national guidance	Acute Services
Caplacizumab 10mg powder and solvent for solution for injection (Cablivi®) SMC Number: 2266 https://www.scottishmedicines.org.uk/media/5367/caplacizumab-cablivi-final-august-2020docx-for-website.pdf	Accepted for use within NHSScotland. Indication under review: Treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.	Category 1 – available in line with national guidance Not added to the FV formulary due to low patient numbers	Acute Services
Mental Health			
Esketamine 28mg nasal spray, solution (Spravato®) SMC Number: 2258 https://www.scottishmedicines.org.uk/media/5353/esketamine-spravato-final-august-2020docx-for-website.pdf	Accepted for use within NHSScotland. Indication under review: In combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.	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 local preference for alternative medicines.	Not applicable

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Microbiology			
<p>Meropenem/vaborbactam 1 gram/1 gram powder for concentrate for solution for infusion (Vaborem®) SMC Number: 2278 https://www.scottishmedicines.org.uk/media/5467/meropenem-vaborbactam-vaborem-final-september-2020-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: for the treatment of the following infections in adults: - Complicated urinary tract infection (cUTI), including pyelonephritis - Complicated intra-abdominal infection (cIAI) - Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Meropenem/vaborbactam is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options. SMC restriction: for adults with confirmed carbapenem-resistant Enterobacteriaceae (CRE), which is involved in the production of <i>Klebsiella pneumoniae</i> carbapenemase (KPC) associated with cUTI (including acute pyelonephritis [AP]), cIAI, HAP (including VAP) and bacteraemia that occurs in association with, or is suspected to be associated with any of the infections previously mentioned. Use should be on the advice of local microbiologists or specialists in infectious disease.</p>	<p>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 local preference for alternative medicines.</p>	<p>Not applicable</p>
Neurology			
<p>Cannabidiol 100mg/ml oral solution (Epidyolex®) SMC Number: 2262 https://www.scottishmedicines.org.uk/media/5365/cannabidiol-epidyolex-ds-final-august-2020docx-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older.</p>	<p>Category 6 – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.</p>	<p>Not applicable</p>
<p>Cannabidiol 100mg/ml oral solution (Epidyolex®) SMC Number: 2263 https://www.scottishmedicines.org.uk/media/5366/cannabidiol-epidyolex-lgs-final-august-2020docx-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older.</p>	<p>Category 6 – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.</p>	<p>Not applicable</p>
<p>Siponimod 250 microgram and 2mg film-coated tablets (Mayzent®) SMC Number: 2265 https://www.scottishmedicines.org.uk/media/5468/siponimod-mayzent-final-september-2020-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity.</p>	<p>Category 1 – available in line with national guidance</p>	<p>Acute Services</p>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Osteoporosis			
Romosozumab 105mg solution for injection in pre-filled pen (Evenity®) SMC Number 2280 https://www.scottishmedicines.org.uk/media/5569/romosozumab-evenity-final-october-2020-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: treatment of severe osteoporosis in postmenopausal women at high risk of fracture. SMC restriction: to use in patients who have experienced a fragility fracture and are at imminent risk of another fragility fracture (within 24 months).	Category 6 – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.	Not applicable
Ophthalmology			
Brolucizumab 120mg/mL solution for injection in pre-filled syringe (Beovu®) SMC Number: 2272 https://www.scottishmedicines.org.uk/media/5364/brolucizumab-beovu-final-august-2020-amended-180820-for-website.pdf	Accepted for use within NHSScotland. Indication under review: in adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).	Category 2 – available in line with local guidance for prescribing	Acute Services
Ex vivo expanded autologous human corneal epithelial cells containing stem cells (Holoclar®) SMC Number: 2261 https://www.scottishmedicines.org.uk/media/5354/ex-vivo-holoclar-final-august-2020-updated-amended-180820-for-website.pdf	Following a full submission for an orphan medicine ex vivo expanded autologous human corneal epithelial cells containing stem cells (Holoclar®) Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: Treatment of adult patients with moderate to severe limbal stem cell deficiency (defined by the presence of superficial corneal neovascularisation in at least two corneal quadrants, with central corneal involvement, and severely impaired visual acuity), unilateral or bilateral, due to physical or chemical ocular burns.	Category 3 – available from a specialist centre in another NHS board	Not applicable
Fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) SMC Number: 2260 https://www.scottishmedicines.org.uk/media/5355/fluocinolone-acetonide-Iluvien-final-august-2020docx-for-website.pdf	Accepted for use within NHSScotland. Indication under review: prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.	Category 1 – available in line with national guidance	Acute Services
Paediatrics			
Hydroxycarbamide 100mg/mL oral solution (Xromi®) SMC Number: 2271 https://www.scottishmedicines.org.uk/media/5278/hydroxycarbamide-xromi-abbreviated-final-july-2020-for-website.pdf	Accepted for restricted use within NHSScotland. Indication under review: for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 2 years of age. SMC restriction: children who are too young to be able to swallow capsules / tablets and adults and adolescents who have difficulty in swallowing solid oral dosage forms.	Category 3 – available from a specialist centre in another NHS board	Not applicable

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Oncology			
<p>Gilteritinib 40mg film-coated tablets (Xospata®) SMC Number: 2252 https://www.scottishmedicines.org.uk/media/5356/gilteritinib-xospata-final-august-2020docx-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation.</p>	<p>Category 1 – available in line with national guidance</p>	<p>Not applicable</p>
<p>Neratinib 40mg film-coated tablets (Nerlynx®) SMC Number: 2251 https://www.scottishmedicines.org.uk/media/5275/neratinib-nerlynx-final-july-2020-for-website.pdf</p>	<p>Accepted for use within NHSScotland. Indication under review: for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.</p>	<p>Category 1 – available in line with national guidance</p>	<p>Not applicable</p>
<p>Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC Number: 2247 https://www.scottishmedicines.org.uk/media/5357/pembrolizumab-keytruda-final-august-2020-amended-270820-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: in combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.</p>	<p>Category 1 – available in line with national guidance</p>	<p>Not applicable</p>
<p>Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC Number: 2257 https://www.scottishmedicines.org.uk/media/5369/pembrolizumab-keytruda-hnsc-cc-final-august-2020docx-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: as monotherapy or in combination with platinum and fluorouracil chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express programmed cell death ligand-1 (PD-L1) with a combined positive score (CPS)≥1. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule</p>	<p>Category 1 – available in line with national guidance</p>	<p>Not applicable</p>
<p>Pertuzumab 420mg concentrate solution for infusion (Perjeta®) SMC Number: 2284 https://www.scottishmedicines.org.uk/media/5359/pertuzumab-perjeta-resub-final-august-2020docx-for-website.pdf</p>	<p>Accepted for restricted use within NHSScotland. Indication under review: for use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence. SMC restriction: for use in patients with lymph node-positive disease</p>	<p>Category 1 – available in line with national guidance</p>	<p>Not applicable</p>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Oncology			
Polatuzumab vedotin 140mg powder for concentrate for solution for infusion (Polivy®) SMC Number: 2282 https://www.scottishmedicines.org.uk/media/5360/polatuzumab-vedotin-polivy-final-august-2020-amended-180820-for-website.pdf	Accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: in combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B--cell lymphoma who are not candidates for haematopoietic stem cell transplant.	Category 1 – available in line with national guidance	Not applicable
SMC NOT RECOMMENDED			
Patiomer (as patiomer sorbitex calcium) 8.4g and 16.8g powder for oral suspension (Veltassa®) SMC Number 2264 https://www.scottishmedicines.org.uk/media/5566/patiomer-veltassa-resub-final-october-2020-for-website.pdf	Not recommended for use within NHSScotland. Indication under review: for the treatment of hyperkalaemia in adults		

Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
Naldemedine 200 micrograms film-coated tablets (Rizmoic®) SMC Number 2242 https://www.scottishmedicines.org.uk/media/5174/insulin-glargine-lixisenatide-suliqua-final-march-2020-amended-010420-for-website-2.pdf	Accepted for use within NHSScotland. Indication under review: For the treatment of opioid induced constipation (OIC) in adult patients who have previously been treated with a laxative	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 (link to local guidance if appropriate)	Not applicable

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](#)

Formulary Changes

Formulary section	Current Product	Changed to	Comments
4.3 - Antidepressants	Phenelzine – removal from formulary	No alternative	There have been supply issues with phenelzine for about a year, Community pharmacies were previously advised to get imported supplies for patients. The imported products are now proving difficult to obtain and this has been flagged up and discussed with the Mental Health specialities. Phenelzine is used in patients with resistant depression and currently no suitable alternatives are available.

Additional Information

Repurposing Guidance Statement: 22 nd September 2020	Guidance is available on the Clinical Guideline section on the intranet under 'COVID' https://guidelines.staffnet.fv.scot.nhs.uk/covid-19/
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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

