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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](http://www.scottishmedicines.org)

### Category Classification

#### **Drugs Approved / Not Recommended By SMC**

<b>Category 1</b>	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
<b>Category 2</b>	Available in line with local guidance for prescribing
<b>Category 3</b>	Available from a specialist centre in another NHS Board
<b>Category 4</b>	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
<b>Category 5</b>	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)
<b>Category 6</b>	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
<b>Endocrinology</b>			
<p><b>Insulin glargine plus lixisenatide (Suliqua®), 100 units/mL plus 50 microgram/mL and 100 units/mL plus 33 micrograms/mL solution for subcutaneous injection in pre-filled pens</b></p> <p><b>SMC Number 2235</b></p> <p><a href="https://www.scottishmedicine.org.uk/media/5174/insulin-glargine-lixisenatide-suliqua-final-march-2020-amended-010420-for-website-2.pdf">https://www.scottishmedicine.org.uk/media/5174/insulin-glargine-lixisenatide-suliqua-final-march-2020-amended-010420-for-website-2.pdf</a></p>	<p><b>Accepted for restricted use</b> within NHSScotland.</p> <p><b>Indication under review:</b> In combination with metformin for the treatment of adults with type 2 diabetes mellitus, to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose-lowering medicinal product or with basal insulin.</p> <p><b>SMC restriction:</b> for use in patients who are uncontrolled on basal insulin (glycosylated haemoglobin [HbA1c] &gt; 7.5% [59mmol/mol]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin analogues.</p>	<p><b>Category 5</b> – 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.</p>	<p><b>Not applicable</b></p>
<b>Gastroenterology</b>			
<p><b>Naldemedine 200 micrograms film-coated tablets (Rizmoic®)</b></p> <p><b>SMC Number 2242</b></p> <p><a href="https://www.scottishmedicines.org.uk/media/5174/insulin-glargine-lixisenatide-suliqua-final-march-2020-amended-010420-for-website-2.pdf">https://www.scottishmedicines.org.uk/media/5174/insulin-glargine-lixisenatide-suliqua-final-march-2020-amended-010420-for-website-2.pdf</a></p>	<p><b>Accepted for use</b> within NHSScotland.</p> <p><b>Indication under review:</b> For the treatment of opioid induced constipation (OIC) in adult patients who have previously been treated with a laxative</p>	<p><b>Category 6</b> – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p><b>Not applicable</b></p>
<p><b>Ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (vials) and solution for injection in pre-filled syringe (Stelara®)</b></p> <p><b>SMC Number 2250</b></p> <p><a href="https://www.scottishmedicines.org.uk/media/5168/ustekinumab-stelara-final-march-2020-amended-010420-for-website.pdf">https://www.scottishmedicines.org.uk/media/5168/ustekinumab-stelara-final-march-2020-amended-010420-for-website.pdf</a></p>	<p><b>Accepted for use</b> within NHSScotland.</p> <p><b>Indication under review:</b> For 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 biologic or have medical contraindications to such therapies.</p>	<p><b>Category 6</b> – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts</p>	<p><b>Not applicable</b></p>
<b>Neurology</b>			
<p><b>Fampridine 10mg prolonged-release tablet (Fampyra®)</b></p> <p><b>SMC Number 2253</b></p> <p><a href="https://www.scottishmedicines.org.uk/media/5165/fampridine-fampyra-final-march-2020-for-website.pdf">https://www.scottishmedicines.org.uk/media/5165/fampridine-fampyra-final-march-2020-for-website.pdf</a></p>	<p><b>Accepted for use</b> within NHSScotland.</p> <p><b>Indication under review:</b> For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).</p>	<p><b>Category 1</b> – available in line with national guidance</p>	<p><b>Secondary Care</b></p>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
<b>Oncology</b>			
<p><b>Blinatumomab 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®)</b>  <b>SMC Number 2234</b>  <a href="https://www.scottishmedicines.org.uk/media/5143/blinatumomab-blinicyto-final-february-2020-for-website.pdf">https://www.scottishmedicines.org.uk/media/5143/blinatumomab-blinicyto-final-february-2020-for-website.pdf</a></p>	<p><b>Accepted for restricted use</b>  <b>Indication under review:</b> As monotherapy for the treatment of adults with Philadelphia chromosome negative, CD19 positive, B-precursor acute lymphoblastic leukaemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.  <b>SMC restriction:</b> to patients who are in first complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.</p>	<p><b>Category 1 –</b>  available in line with national guidance</p>	<p><b>Secondary Care or Tertiary Centre</b></p>
<p><b>Lorlatinib 25mg and 100mg film-coated tablets (Lorviqua®)</b>  <b>SMC Number 2239</b>  <a href="https://www.scottishmedicines.org.uk/media/5145/lorlatinib-lorviqua-final-february-2020-for-website.pdf">https://www.scottishmedicines.org.uk/media/5145/lorlatinib-lorviqua-final-february-2020-for-website.pdf</a></p>	<p><b>Accepted for use</b> on an interim basis subject to ongoing evaluation and future reassessment.  <b>Indication under review:</b> as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after:  - alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or  - crizotinib and at least one other ALK TKI</p>	<p><b>Category 1 –</b>  available in line with national guidance</p>	<p><b>Tertiary Centre</b></p>
<p><b>Rucaparib 200mg, 250mg, 300mg film-coated tablets (Rubraca®)</b>  <b>SMC Number 2224</b>  <a href="https://www.scottishmedicines.org.uk/media/5147/rucaparib-rubraca-final-february-2020-for-website.pdf">https://www.scottishmedicines.org.uk/media/5147/rucaparib-rubraca-final-february-2020-for-website.pdf</a></p>	<p><b>Accepted for restricted use</b>  <b>Indication under review:</b> As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.  <b>SMC restriction:</b> to patients who do not have a BRCA mutation</p>	<p><b>Category 1 –</b>  available in line with national guidance</p>	<p><b>Tertiary Centre</b></p>
<b>Not Recommended</b>			
<p><b>Cinacalcet hydrochloride 1mg, 2.5mg and 5mg granules in capsules for opening (Mimpara®)</b>  <b>SMC Number 2275</b>  <a href="https://www.scottishmedicines.org.uk/media/5144/cinacalcet-mimpara-non-sub-final-february-2020-for-website.pdf">https://www.scottishmedicines.org.uk/media/5144/cinacalcet-mimpara-non-sub-final-february-2020-for-website.pdf</a></p>	<p><b>Indication under review:</b>  <u>Secondary hyperparathyroidism (HPT)</u>  ○ Treatment of secondary HPT in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy.  ○ Treatment of secondary HPT in children aged 3 years and older with ESRD on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy  <u>Parathyroid carcinoma and primary HPT in adults</u>  ○ Reduction of hypercalcaemia in adult patients with:  - parathyroid carcinoma.  - primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated</p>	<p><b>Category 4 –</b> not available as not recommended for use in NHSScotland for his indication</p>	<p><b>Not applicable</b></p>

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
<b>Not Recommended</b>			
<b>Mexiletine 167mg hard capsules (Namuscla®)</b> <b>SMC Number 2241</b> <a href="https://www.scottishmedicines.org.uk/media/5149/mexiletine-namuscla-final-february-2020-amended-030320-for-website.pdf">https://www.scottishmedicines.org.uk/media/5149/mexiletine-namuscla-final-february-2020-amended-030320-for-website.pdf</a>	<b>Indication under review:</b> for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders.	<b>Category 4</b> – not available as not recommended for use in NHSScotland for this indication	<b>Not applicable</b>
<b>Ranibizumab 10mg/mL solution for injection (Lucentis®)</b> <b>SMC Number 2274</b> <a href="https://www.scottishmedicines.org.uk/media/5146/ranibizumab-lucentis-non-sub-final-feb-2020-for-website.pdf">https://www.scottishmedicines.org.uk/media/5146/ranibizumab-lucentis-non-sub-final-feb-2020-for-website.pdf</a>	<b>Indication under review:</b> In preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease.	<b>Category 4</b> – not available as not recommended for use in NHSScotland for this indication	<b>Not applicable</b>

### Changes on ADTC decisions for SMC approved Drugs

Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
<b>Trientine tetrahydrochloride (equivalent to 150 mg trientine) film-coated tablets (Cuprior®)</b> <b>SMC No 2222</b> <a href="https://www.scottishmedicines.org.uk/media/4889/trientine-tetrahydrochloride-cuprior-abbreviated-final-oct-2019-for-website.pdf">https://www.scottishmedicines.org.uk/media/4889/trientine-tetrahydrochloride-cuprior-abbreviated-final-oct-2019-for-website.pdf</a>	<b>Accepted for use within</b> <b>Indication under review:</b> the treatment of Wilson's disease in adults, adolescents and children ≥5 years intolerant to D-penicillamine therapy.	<b>Category 6</b> – not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	<b>Category 5</b> – 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	<b>Not applicable</b>

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

