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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 an Individual Patient Treatment Request (IPTR) process which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to seek 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

If a clinician requests the addition of a medicine to the formulary a New Medicines Proforma should be completed.
This is available on the link below.
http://staffnet.fv.scot.nhs.uk/index.php/a-z/pharmacy/area-wide/formulary/

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the Quality Improvement Website, link below.

http://www.qifv.scot.nhs.uk/

RIVAROXABAN

Rivaroxaban has been approved for use in Forth Valley for **Atrial Fibrillation and DVT**, the guidelines can be found on the Quality Improvement website using the search term 'Rivaroxaban'.

ADRENALINE AUTO INJECTORS

Due to the problems with Anapen® injector pens, the pen of choice in Forth Valley is Epipen®

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 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 Scottish Medicines Consortium (SMC)/New Drugs Committee (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.

The SMC has advised that the following drugs are **not** recommended for use in NHS Scotland.

Generic Name & Formulation	Brand Name	Indication
Adalimumab	*Humira®*	Treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies
Argatroban, 100mg/ml, concentrate for solution for infusion	*Exembol®*	Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy A statement was issued by the SMC which is outlined below: SMC considered this submission for argatroban on Tuesday 2nd October and has issued a "Not Recommended" advice. The committee were made aware, however, of the challenges around availability of other treatments. Lepirudin has recently been withdrawn from the market for commercial reasons and subsequently there have been intermittent supply problems with danaparoid. These products will be required urgently for acutely ill patients with heparin induced thrombocytopenia and Health Boards may wish to ensure that the systems and processes in place will allow appropriate access for patients. ---------- As this may be required urgently for patients it is proposed within Forth Valley, that acute services will keep a quantity in stock and an Individual Patient Treatment Request (IPTR) will be completed retrospectively for any patient who may require this medicine

Generic Name & Formulation	Brand Name	Indication
Brentuximab vedotin 50mg powder for concentrate for solution for infusion	*Adcetris®*	Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL)
Caffeine citrate 20mg/mL solution for infusion and oral solution	*Peyona®*	Treatment of primary apnoea of premature newborns
Decitabine 50mg powder for concentrate for solution for infusion	*Dacogen®*	Treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy
Etoricoxib 30mg, 60mg, 90mg & 120mg film coated tablets	*Arcoxia®*	Short-term treatment of moderate pain associated with dental surgery
Hydrocortisone 5mg and 20mg tablets	*Plenadren®*	Treatment of adrenal insufficiency in adults
Interferon beta-1a	*Rebif®*	Patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis
Ivacaftor 150mg film-coated tablets	*Kalydeco®*	Treatment of cystic fibrosis (CF) in patients age 6 years and older who have a *G551D* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
Pasireotide 0.3mg, 0.6mg and 0.9mg dilution for injection	*Signifor®*	Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed
Pazopanib 200mg, 400mg film-coated tablets	*Votrient®*	For the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. Efficacy and safety has only been established in certain STS histological tumour subtypes
Racecadotril 10mg, 30mg granules for oral suspension	*Hidrasec Infants®* *Hidrasec Children®*	Complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children. Together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition
Racecadotril 100mg capsule	*Hidrasec®*	Symptomatic treatment of acute diarrhoea in adults when casual treatment is not possible
Tadalafil 5mg film coated tablets	*Cialis®*	Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males
Ranolazine, 375mg, 500mg and 750mg prolonged-release tablets [Independent Review Panel (IRP)]	*Ranexa®*	As add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists)
Stontium ranelate 2g granules for oral suspension	*Protelos®*	Treatment of osteoporosis in men at increased risk of fracture
Tocofersolan, 50mg/mL (corresponding to 74.5 IU tocopherol) oral solution	*Vedrop®*	Vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region
Zonisamide 25, 50, 100mg Hard Capsules	*Zonegran®*	Monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy

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 manufacturer to resubmit the drug to SMC with new evidence.

NICE Multiple Technology Appraisal (MTA): NHS Quality Improvement Scotland (NHS QIS) reviews MTAs and decides whether the recommendations should apply in Scotland. Where Health 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
NICE (Single) Technology Appraisal Guidance No 264 – Alteplase for treating acute ischaemic stroke (review of technology appraisal guidance 122)	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA264**	**Accepted for use** **Indication under review** – the fibrinolytic treatment of acute ischaemic stroke. Treatment must be started as early as possible within 4.5 hours after onset of the stroke symptoms and after exclusion of intracranial haemorrhage by appropriate imaging techniques (e.g. cranial computerized tomography or other diagnostic imaging method sensitive for the presence of haemorrhage).	**11/6/12**	**Yes**

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA265**	**Not recommended** **Indication** – prevention of skeletal related events (pathological fracture, radiation to the bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours.	**12/12/11**	**Yes** **Restricted to specialist recommendation in secondary care in women only**

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**

Drugs Approved By SMC

The ADTC recommends that prescribers may prescribe these drugs in accordance with SMC advice.

Many drugs are approved for use or restricted use by SMC but are not included in the formulary.

If appropriate these drugs can be prescribed for suitable patient's outwith the formulary choices.

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Aclidinium 322 micrograms inhalation powder *(Eklira Genuair®*	**Accepted for use** **Indication under review:** as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)	**Not included in the formulary**
5-aminolaevulinic acid (as hydrochloride), 78mg/g, gel *(Ameluz®)*	**Accepted for use** **Indication under review:** treatment of actinic keratosis of mild to moderate intensity on the face and scalp	**Not included in the formulary**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Bortezomib 3.5mg powder for subcutaneous injection *(Velcade®)* **Product Update**	**Accepted for use** **Indication under review:** in combination with melphalan and prednisolone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant	**Already included in the formulary**
Budesonide 3mg gastro-resistant capsule *(Budenofalk®)*	**Accepted for use** **Indication under review:** symptomatic relief of chronic diarrhoea due to collagenous colitis	**Not included in the formulary**
Budesonide 9mg gastro-resistant granules *(Budenofalk®)* **Product Update**	**Accepted for use** **Indication under review:** induction of remission in patients with active collagenous colitis	**Not included in the formulary**
Ceftaroline fosamil, 600mg, powder for concentrate for solution for infusion *(Zinforo®)*	**Accepted for restricted use** **Indication under review:** treatment of complicated skin and soft tissue infections in adults **SMC restriction**: use in patients with known or suspected meticillin resistant resistant *Staphylococcus aureus* (MRSA) infection in the following settings • For Gram-positive only infections where vancomycin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv or linezolid iv is normally used. • For polymicrobial Gram-positive and common Gram-negative pathogens, where vancomycin iv in combination with gentamicin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv in combination with gentamicin iv, or linezolid iv in combination with gentamicin iv, or tigecycline iv is normally used	**Not included in the formulary**
Clostridium botulinum type A toxin-haemagglutinin complex 300 units and 500 units *(Dysport®)* **Re-submission**	**Accepted for restricted use** **Indication under review:** for focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy **SMC restriction**: for focal spasticity of the upper limbs associated with stroke	**Included in the formulary for specialist use**
Dapagliflozin 5mg and 10mg film-coated tablets *(Forxiga®)*	**Accepted for restricted use** **Indication under review:** for use in adults aged 18 years older with type 2 diabetes mellitus to improve glycaemic control as: <u>Add-on combination therapy</u> In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control **SMC restriction**: Dapaglifozin is restricted to use as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate	**Not included in the formulary**
Fluticasone proprionate and formoterol metered dose inhaler, 50microgam/5microgram, 125microgram/5 microgram 250microgram/10microgram *(Flutiform®)*	**Accepted for use** **Indication under review:** in the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting beta2 agonist (LABA)] is appropriate: • For patients not adequately controlled on ICS and 'as required' inhaled short-acting Beta2-agonist or • For patients already adequately controlled on both an ICS and a LABA	**Included in the formulary for indication in question**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Glycopyrronium 44 micrograms hard capsules of inhalation powder *(Seebri Breezhaler®)*	**Accepted for use** **Indication under review:** as maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)	**Pending Awaiting outcome of discussions at Respiratory MCN**
Ivabradine 5 and 7.5mg film-coated tablets *(Procoralan®)*	**Accepted for restricted use** **Indication under review:** chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ beats per minute (bpm), in combination with standard therapy including bets-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated **SMC restriction**: for initiation only in patients whose resting heart rate remains ≥ beats per minute despite optimal standard therapy	**Not included in the formulary**
Lanthanum carbonate 750mg and 1000mg oral powder *(Fosrenol®)* **Product Update**	**Accepted for restricted use** **Indication under review:** as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD) Lanthanum is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels >1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels **SMC restriction:** as a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required	**Already included in the formulary**
Nepafenac 1mg/mL eye drops, suspension *(Nevanac®)*	**Accepted for use** **Indication under review:** reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients	**Not included in the formulary**
Olmesartan medoxomil / amlodipine besilate/ hydrochlorothiazide **Product Update**	**Accepted for use** **Indication under review:** in adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation	**Not included in the formulary**
Perampanel, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film coated tablets *(Fycompa®)*	**Accepted for restricted use** **Indication under review:** adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older **SMC restriction**: use as second-line adjunctive treatment in patients with refractory partial onset epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy	**Not included in the formulary**
Ranibizumab, 10mg/mL solution for injection *(Lucentis®)* **Re-Submission**	**Accepted for restricted use** **Indication under review:** treatment of visual impairment due to diabetic macular oedema (DMO) in adults **SMC restriction**: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline	**Already included in the formulary**
Sildenafil (as citrate) 20mg film-coated tablets and 10mg/mL powder for oral solution *(Revatio®)* **Product Update**	**Accepted for restricted use** **Indication under review:** treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease **SMC restriction**: restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service	**Included in the formulary - Continuation of therapy from tertiary centres**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Velaglucerase alfa 400 units powder for solution for infusion *(VPRIV®)*	**Accepted for use** **Indication under review:** Long-term enzyme replacement therapy in patients with type 1 Gaucher disease	**Not included in the formulary**
Vildagliptin 50mg tablets *(Galvus®)*	**Accepted for restricted use** **Indication under review:** treatment of type 2 diabetes mellitus in adults as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance **SMC restriction:** for use in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications of intolerance	**Not included in the formulary**

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