



Special points of interest for Primary Care

- Thromboprophylaxis – non-valvular AF
- Rivaroxaban, apixaban, dabigatran - risk of serious bleeding

SMC advice:

- Bimatoprost plus timolol (Ganfort® Unit Dose Preservative Free)
- Botulinum toxin type A (Botox®)
- Carglumic acid (Carbaglu®)
- Crizotinib (Xalkori®)
- Granisetron (Sancuso®)
- Imatinib (Glivec®)
- Nalmefene (Selincro®)
- Pertuzumab (Perjeta®)
- Vismodegib (Erivedge®)

Updates from previous SMC advice:

- Rituximab (MabThera®)
- Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil (Stribild®)



Specialist lists - progress

The Obstetrics & Gynaecology specialist list has been finalised. This list includes several medicines that may be prescribed in General Practice, under the direction of a specialist, such as metformin for polycystic ovary syndrome, ulipristal acetate, clomifene, goserelin, labetalol and nifedipine MR for hypertension in pregnancy, domperidone for augmentation of lactation, imiquimod for vulval intraepithelial neoplasia and tamoxifen for anovulatory infertility.

The list also includes several hospital-only medicines such as spironolactone, cyproterone acetate and finasteride for hirsutism in postmenopausal women.

Medicines from this list will not be incorporated into the current core formulary, but will be included in the formulary once launched on the new netFormulary platform.

The [Obstetrics & Gynaecology specialist formulary list](#) can currently be accessed as with other specialist lists from the [Tayside Area Formulary](#) website.



Guidelines and Protocols

Thromboprophylaxis - non-valvular AF

A [Tayside approach to thromboprophylaxis for patients with non-valvular atrial fibrillation \(AF\)](#) has now been finalised, giving clear guidance on when warfarin or the newer oral anticoagulants (NOACs) should be used for non-valvular AF.

Remember :

- If CHA_2DS_2 - VASc score equals - zero, then no oral anticoagulant
- Warfarin 1st line and in patients with eGFR below 30mL/min/m²
- Consider NOACs if poor INR control, allergy or intolerance to warfarin, difficulty in monitoring INR (e.g. rural location, house-bound) or pre & post cardioversion
- Rivaroxaban 1st choice NOAC & apixaban 2nd choice
- Monitor renal function before starting any NOAC & at least annually
- Non compliance alone is not an indication for initiating NOACs

Rarely Used Urgent Medicines (RUUM) List

The newly launched Rarely Used Urgent Medicines (RUUM) list is a list of agreed stock holding locations of infrequently used medicines created to support hospital pharmacy staff within NHS Scotland in providing access to medicines.

The list is intended primarily to support staff on call during the out of hours period when conventional supply routes are unavailable but could also be used during normal working hours if usual supply routes could result in delays to patient care. The list is not intended to bypass usual procurement routes and is not intended for use by, or distribution to non-pharmacy staff.

The list is accessible via TOXBASE (<http://www.toxbase.org/>) after login. Further information and a link to TOXBASE has been added to the current Tayside Area Formulary within Chapter 18 - Emergency Treatment of Poisoning and a link will be included in the formulary once launched on the new netFormulary platform.

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Drug Safety Updates

Please follow link - [Volume 7, Issue 3, October 2013](#)

Rivaroxaban, apixaban & dabigatran - risk of serious bleeding

Haemorrhage is a common adverse effect of all anticoagulants. As a result of a European review – all 3 new oral anticoagulants (i.e. rivaroxaban, apixaban & dabigatran) now have the same contraindications in patients with conditions putting them at significant risk of major bleeding, and those relating to use with other concomitant anticoagulants. This applies for all indications and doses.

The following contraindications now apply:

- A lesion or condition, if considered a significant risk factor for major bleeding. This may include:
 - current or recent GI ulceration
 - presence of malignant neoplasm at high risk of bleeding
 - recent brain or spinal injury
 - recent brain, spinal or ophthalmic surgery
 - recent intracranial haemorrhage
 - known or suspected oesophageal varices
 - arteriovenous malformation
 - vascular aneurysms or major intraspinal or intracerebral vascular abnormalities
- Concomitant treatment with any other anticoagulant agent. Examples include:
 - unfractionated heparin
 - low molecular weight heparin (such as enoxaparin or dalteparin)
 - heparin derivatives (such as fondaparinux)
 - oral anticoagulants (such as warfarin)

Exceptions are switching of therapy to or from the new oral anticoagulants (NOACs).

Special care should be taken when considering prescribing NOACs to patients with other conditions, procedures or treatments (e.g. NSAIDs or antiplatelets) which may increase the risk of major bleeding.

See [Drug Safety Update volume 7 issue 3, October 2013](#) for further information.

There is no antidote to rivaroxaban, apixaban or dabigatran for the management of major bleeding. The drug should be stopped and the on call haematologist / blood transfusion service should be contacted for further advice.

Refer to [Tayside guidance for management of patients on rivaroxaban or apixaban](#) and individual SPCs for further information on the management of bleeding.

Medicine	Indication	Local recommendation category	Comments and useful links
Bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eye-drops (Ganfort® Unit Dose Preservative Free) (906/13) - Abbreviated submission	For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. SMC restriction: to use in patients who have proven sensitivity to preservatives.	GP under direction of Ophthalmology Ophthalmology Specialist List Restricted to use in patients who can not tolerate preservative.	SMC advice SPC link Non preservative free bimatoprost / timolol eye drops are non formulary
Botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®) (916/13) - Full submission	Management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required.	Hospital Only Urology Specialist List	SMC advice SPC link (50 units) SPC link (100 units) SPC link (200 units)
Carglumic acid 200mg dispersible tablets (Carbaglu®) (899/13) - Full submission	Hyperammonaemia due to isovaleric acidemia, methylmalonic acidemia and propionic acidemia.	Hospital Only Under recommendation of a specialist in metabolic disorders	SMC advice SPC link
Crizotinib, 200mg and 250mg, hard capsule (Xalkori®) (865/13) - Resubmission	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Hospital Only (Oncology)	SMC advice SPC link
Granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) (895/13) - Abbreviated submission	In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult.	Hospital Only Non-chemo Haematology & Oncology Specialist List	SMC advice SPC link
Imatinib (Glivec®) 100 mg / 400 mg film coated tablets (923/13) - Non-submission	Treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.	Not recommended	SMC advice
Nalmefene 18mg film-coated tablets (Selincro®) (917/13) - Full submission	The reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.	Non-Formulary - protocol pending	SMC advice SPC link
Pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) (897/13) - Full submission	For use in combination with trastuzumab and docetaxel in adult patients with human epidermal growth factor-2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	Not recommended	SMC advice

'Local processes exist to allow consideration of prescribing outwith SMC advice or outwith NHS Tayside formulary. Details are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#)'

* 'pending' means that no local recommendation to support use is in place at the current time

Medicine	Indication	Local recommendation category	Comments and useful links
Vismodegib (Erivedge®) 150 mg hard capsules (924/13) - <i>Non-submission</i>	Treatment of adult patients with: <ul style="list-style-type: none"> symptomatic metastatic basal cell carcinoma locally advanced basal cell carcinoma inappropriate for surgery or radio-therapy 	Not recommended	SMC advice

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg film coated tablet (Stribild®) (887/13) - <i>Full submission</i>	Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®.	Hospital Only, HIV clinic 3rd line Supplied via a Patient Access Scheme (PAS)	SMC advice SPC link
Rituximab 100mg, 500mg solution for infusion (MabThera®) (894/13) - <i>Full submission</i>	In combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). SMC restriction: to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide.	Hospital Only Rheumatology & Renal specialist list 2nd line	SMC advice SPC link <i>Protocol pending</i>

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Tayside Area Formulary (TAF) Updates - Oct/Nov 2013

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Obstetrics & Gynaecology	Obstetrics & Gynaecology specialist formulary list added.
4 - Central Nervous System Guidelines	Pain Guidance Notes	Links to the following guidelines added to this section (already included in section 4.7): Guideline on the use of Strong Opioids for Chronic Non-malignant Pain , NHS Tayside Pain Management Guidelines Book , NHS Tayside Acute Pain Service Guidance for management of anticipated complex pain .
4.6 Oncology & Haematology specialist list – non-chemotherapy drugs	Nausea and vomiting induced by chemotherapy	Granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) added to formulary and Oncology & Haematology specialist formulary list – non-chemotherapy drug (hospital only). See SMC advice (page 3) for further information.
7.4.2 Urology specialist list	Drugs for urinary frequency (in the absence of outflow obstruction), urgency and incontinence	Botulinum toxin type A (Botox®) added to formulary and Urology specialist formulary list (hospital only). See SMC advice (page 3) for further information.
9.2 Renal specialist list	Potassium citrate	Potassium citrate mixture BP (approx. 1mmol/mL of citrate) (for prescribing under the direction of a Renal specialist) and potassium citrate 1080mg tablets (10mmol of citrate) (unlicensed) (hospital only) added to formulary and Renal specialist formulary list for reduction of renal stone formation including patients with hypocitraturia and renal tubular acidosis. Potassium citrate tablets restricted to patients who do not tolerate potassium citrate mixture.
10.1.3 Rheumatology specialist list Renal specialist list	Rituximab	Rituximab 100mg, 500mg solution for infusion (MabThera®) added to formulary, Rheumatology specialist formulary list, and Renal specialist formulary list (hospital only). See SMC advice (page 4) for further information.
18	Emergency Treatment of Poisoning	New section added. Note added: In the event of poisoning the National Poisons Information Service should be contacted. Link to TOXBASE (password protected) and information on the Rarely Used Urgent Medicines (RUUM) List added.
20	Guidelines for the Perioperative Management of Patients with Diabetes	Information in section replaced with link to current guidance: Peri-operative Diabetes Management Guideline and Intravenous Insulin Management Guideline .

SMC Briefing Note:
[Click here](#) for October Briefing Note

[Forthcoming SMC Advice](#)

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Drug and Therapeutics Committee.

Please direct any queries to either:

Karen Harkness
Principal Pharmacist - Clinical Effectiveness
email: kharkness@nhs.net

or

Claire James
Senior Pharmacist - Clinical Effectiveness
email: clairejames@nhs.net

Local implementation of SMC recommendations is taken forward by the Tayside Medicines Governance Unit. This bulletin is based on evidence available to the Tayside Medicines Governance Unit at time of publication and is covered by the Disclaimer and Terms & Conditions of use.

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