



Special Points of Interest for Primary Care

SMC Advice - July:

- Adalimumab (Humira®)
- Ceftobiprole (Zevtera®)
- Darunavir (Prezista®)
- Magnesium aspartate dihydrate (Magnaspartate®)
- Olaparib (Lynparza®)
- Panitumumab (Vectibix®)
- Posaconazole (Noxafil®)
- Riociguat (Adempas®)
- Rivaroxaban (Xarelto®)
- Sorafenib (Nexavar®)
- Tinzaparin (Innohep Syringe®)
- Vedolizumab (Entyvio®)
- Vinflunine (Javlor®)

SMC Advice - August:

- Darunavir/cobicistat (Rezolsta®)
- Enzalutamide (Xtandi®)
- Eribulin (mesilate) solution for injection (Halaven®)
- Palonosetron hydrochloride (Aloxi®)
- Tedizolid phosphate (Sivextro®)
- Tiotropium (Spiriva® Respimat®)

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Specialist List Updates

Cardiology

The Cardiology Specialist Formulary List has been reviewed along with Chapter 2 (Cardiovascular system) of the formulary. Changes include addition of fluvastatin and minoxidil for prescribing by GPs under the direction of the Cardiovascular risk clinic (Amber traffic light).

As part of this review, the algorithms for reviewing patient's prescribed ezetimibe have been updated to take into account the change from simvastatin to atorvastatin and to ensure they are consistent with current recommendations. The updated algorithms can be accessed from the ezetimibe entry in the [Tayside Area Formulary](#).

Guidance on aggressive lipid lowering in acute coronary syndrome has also been updated to take into account the change in statin formulary choice. The updated guidance can be accessed from the atorvastatin entry in the Tayside Area Formulary - [CLICK HERE](#).



Guidelines and Protocols

Amiodarone Shared Care Agreement

Oral amiodarone should be initiated only under hospital or specialist supervision and is an amber traffic light in the Tayside Area Formulary (TAF).

A [Shared Care Agreement \(SCA\) for amiodarone tablets](#) has been developed by cardiology specialists from NHS Tayside after wide consultation across both primary & secondary care and approved by the Area Drug and Therapeutic Committee.

It is hoped that this SCA will improve the safer use of amiodarone with more consistent monitoring across NHS Tayside.

There is clear guidance on dosing, adverse effects, drug interactions and monitoring required by both secondary and primary care.

Amiodarone has been added to the Near Patient Testing Locally Enhanced Scheme (NPT-LES) to cover the monitoring of liver function tests and thyroid function tests in primary care. Patients should be advised to inform their optometrist that they are taking amiodarone and to attend for annual eye examinations.

A [Patient Information Leaflet](#) has also been developed to inform patients of the common issues regarding amiodarone tablets including side effect profile, drug interactions, required monitoring, what to do if they miss a dose and who to contact locally for further information.

There is a risk of severe bradycardia or heart block when amiodarone is used in combination with some medicines used to treat hepatitis C. Information on the interactions have been added to the SCA.

Parkinson's in Hospital

Guidance for acute units on prescribing of Parkinson's medicines where the oral route is compromised/unavailable has been developed and agreed by the Tayside Parkinson's group. [CLICK HERE](#) to access document.

This will be searchable from the Tayside Area Formulary.



Drug Safety Updates

Please follow link for Drug Safety Updates: [July 2015](#) | [August 2015](#)

High Dose Ibuprofen – New Contra-indications

High dose ibuprofen ($\geq 2400\text{mg/day}$) is known to be associated with an increased risk of thrombotic events. The MHRA and other EU medicines regulators have reviewed the safety of high dose ibuprofen ($\geq 2400\text{mg/day}$) and confirmed that this higher risk is similar to that seen with COX-2 inhibitors and diclofenac (see [MHRA Drug Safety Update article - High dose ibuprofen: small increase in cardiovascular risk, June 2015](#)).

High dose ibuprofen ($\geq 2400\text{mg/day}$) is now contraindicated in patients with established:

- Ischaemic heart disease
- Peripheral arterial disease
- Cerebrovascular disease
- Congestive heart failure (New York Heart Association [NYHA] classification II-III)
- Uncontrolled hypertension

Patients on high dose ibuprofen with the above conditions should have their treatment reviewed at the next clinic appointment. The Tayside Area Formulary entry for ibuprofen has been updated to reflect the above advice.

Denosumab and i.v. bisphosphonates - Patient Reminder Cards

Patient reminder cards are being introduced for denosumab and i.v. bisphosphonates to inform patients of the risks of osteonecrosis of the jaw (ONJ). [CLICK HERE](#) for sample text.

The patient reminder cards will be available to order directly from the manufacturer or to print from the eMC.

They are already available for denosumab 60mg (Prolia[®]) for osteoporosis and denosumab 120mg (Xgeva[®]) for Oncology patients (SMC not recommended).

They are expected to be available by the last quarter of 2015 for both formulations of zoledronic acid (Aclasta[®] & Zometa[®]) and disodium pamidronate (Aredia[®]).



Prescribing Changes

netFormulary Chapter 13: Skin

Medicines within [Chapter 13: Skin](#), of the formulary are now available in the netFormulary format. However, many of the formulary sections within Chapter 13 are currently under review (and this is stated within each relevant section) including: 13.03 Topical local anaesthetics and antipruritics; 13.04 Topical corticosteroids; 13.05 Preparations for eczema and psoriasis (including drugs affecting the immune response); 13.06 Acne and rosacea; 13.07 Preparations for warts and calluses; 13.09 Shampoos and other preparations for scalp and hair conditions; 13.10 Anti-infective skin preparations; 13.12 Hyperhidrosis; and 13.13 Circulatory preparations.

Asthma Inhaled Medicine Chart

The Respiratory MCN Adult Asthma Group have updated the [inhaled medicine chart for asthma](#). This outlines choices of inhaled medicines at each treatment step. The chart reinforces formulary choices of inhaled medicines for asthma and provides options at each step based upon the device that is best suited to the individual patient, either an MDI or Dry powder inhaler. The updated chart is linked from Chapter 3 of the [Tayside Area Formulary](#).

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
adalimumab 40 mg/0.8 ml solution for injection (Humira®) SMC No. (1068/15) Abbreviated Submission	Treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.	Non Formulary Lack of clinician demand	SMC advice SPC link
ceftobiprole, 500mg, powder for concentrate for solution for infusion (Zevtera®) SMC No. (943/14) Resubmission	Indicated for the treatment of the following infections in adults: - Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) - Community-acquired pneumonia (CAP) SMC restriction: for use in the treatment of HAP (excluding VAP) when activity is required against suspected methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) and Gram-negative pathogens (including <i>Pseudomonas aeruginosa</i> , <i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i>) and when combination treatment that includes vancomycin or teicoplanin is inappropriate or has not been tolerated, or when treatment modification is required, i.e. as an alternative to linezolid-based regimens.	Hospital Use Only Needs approved by Infectious Disease or Microbiology ALERT antibiotic	SMC advice SPC link
darunavir 75mg, 150mg, 400mg, 600mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) SMC No. (1069/15) Abbreviated Submission	Once daily darunavir co-administered with low dose ritonavir in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients aged 3 to 12 years and ≥15kg who are 1) treatment-naïve or 2) treatment-experienced with no darunavir resistance-associated mutations, plasma-HIV-1 RNA <100,000 copies/mL, and CD4+ count >100×10 ⁶ cells/L.	Hospital Only (Paediatric HIV clinic)	SMC advice SPC links: oral suspension 400mg & 800mg 75mg, 150mg & 600mg
magnesium aspartate dihydrate equivalent to 243mg (10mmol) of magnesium powder for oral solution (Magnaspartate®) SMC No. (1042/15) Abbreviated Submission	For the treatment and prevention of magnesium deficiency, as diagnosed by a doctor	Formulary	SMC advice SPC link
olaparib, 50mg, hard capsules (Lynparza®) SMC No. (1047/15) Full Submission	Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.	Not Recommended	SMC advice
panitumumab (Vectibix®) SMC No. (1082/15) Non Submission	Treatment of adult patients with wild-type RAS metastatic colorectal cancer first-line in combination with FOLFIRI.	Not Recommended	SMC advice

* '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
posaconazole 300mg concentrate for solution for infusion (Noxafil®) SMC No. (1067/15) Abbreviated Submission	For use in the treatment of the following fungal infections in adults: - Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; - Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; - Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; - Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. For prophylaxis of invasive fungal infections (IFI) in the following patients: - Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing IFI; - Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high risk of developing IFI.	Formulary Haematology patients who require oral posaconazole for prophylaxis, but oral route is not available Otherwise needs approved by Infectious Diseases/Microbiology	SMC advice SPC link
riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®) SMC No. (1056/15) Full Submission	Pulmonary arterial hypertension (PAH): as monotherapy or in combination with endothelin receptor antagonists, for the treatment of adult patients with PAH with World Health Organisation Functional Class (WHO FC) II to III to improve exercise capacity.	Hospital Only (Under the direction of the Scottish Pulmonary Vascular Centres)	SMC advice SPC link
rivaroxaban 2.5mg film-coated tablets (Xarelto®) SMC No. (1062/15) Full Submission	Rivaroxaban co-administered with aspirin alone or with aspirin plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.	Not Recommended	SMC advice

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

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#).

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
sorafenib 200mg film-coated tablets (Nexavar®) SMC No. (1055/15) Full Submission	For the treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.	Non Formulary pending specialist decision	SMC advice SPC link
tinzaparin 20,000 IU/ml 0.4ml, 0.5ml, 0.6ml, 0.7ml, 0.8ml and 0.9ml pre-filled syringe (Innohep Syringe®) SMC No. (1061/15) Full Submission	Patients with solid tumours: Extended treatment of symptomatic venous thrombo-embolism (VTE) and prevention of its recurrence.	Non Formulary pending specialist decision	SMC advice SPC link
vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) SMC No. (1064/15) Full Submission	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.	Hospital Use Only under direction of GI specialist (GI Specialist formulary list)	SMC advice SPC link
vinflunine (as ditartrate), 25mg/mL, concentrate for solution for infusion (Javior®) SMC No. (686/11) Resubmission	Monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen	Not Recommended	SMC advice

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
darunavir 800mg /cobicistat 150mg film-coated tablet (Rezolsta®) SMC No. (1081/15) Full Submission	In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use.	Formulary Hospital Only (HIV Clinic)	SMC advice SPC link
enzalutamide 40mg soft capsules (Xtandi®) SMC No. (1066/15) Full Submission	Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Not Recommended	SMC advice
eribulin (mesilate) 0.44mg/mL, solution for injection (Halaven®) SMC No. (1065/15) Full Submission	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.	Not Recommended	SMC advice

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

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#).

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
palonosetron hydrochloride 250 micrograms solution for injection (Aloxi®) SMC No. (1073/15) Abbreviated Submission	For the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, in paediatric patients 1 month of age and older.	Non Formulary pending specialist decision	SMC advice SPC link
tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®) SMC No. (1080/15) Full Submission	Use in adult patients with acute bacterial skin and skin structure infections (ABSSSI). SMC restriction: ABSSSI caused by Gram-positive <i>Staphylococcus aureus</i> (specifically methicillin-resistant <i>Staphylococcus aureus</i> [MRSA] isolates). Tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacterial on the specific advice of local microbiologists or specialists in infectious disease.	Non formulary pending specialist decision	SMC advice SPC link - tablets SPC link - infusion
tiotropium 2.5 microgram solution for inhalation (Spiriva® Respimat®) SMC No. (1028/15) Full Submission	As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta ₂ agonists and who experienced one or more severe exacerbations in the previous year.	Formulary GP prescribing under direction of respiratory clinic (Respiratory Specialist formulary list)	SMC advice SPC link

Updates from previous SMC Advice

No updates this month



Tayside Area Formulary (TAF) Updates - August 2015

TAF Section	Drug(s)/Topic	Changes
Specialist Formulary Lists	Cardiology	Cardiology specialist formulary list reviewed and updated. Fluvastatin and minoxidil added for prescribing by GPs under the direction of the Cardiovascular Risk Clinic (Amber traffic light).
01.05.03	Vedolizumab	Indication for adults with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to adalimumab or infliximab added to vedolizumab (Entyvio®) formulary entry and Gastroenterology specialist formulary list (Hospital Only). See SMC advice on page 5.
Chapter 2	Cardiovascular system	Links to CCU therapeutic schedule removed throughout. Links to Tayside Cardiology protocol - Management of patients with Atrial Fibrillation (Staffnet intranet link only) updated throughout to current version in use.
02.05.01	Vasodilator antihypertensive drugs	Minoxidil added to formulary and Cardiology specialist formulary list for prescribing by GPs for severe resistant hypertension in combination with a beta-blocker and adequate dose of diuretic under the direction of the Cardiovascular risk clinic (Amber traffic light).
02.06.01	Nitrates	Links to GTN protocol for management of chest pain where GTN Suscard Buccal is not available removed as out of date. Addition of M/R tablets as formulation of isosorbide mononitrate.
02.08.02	Oral anticoagulants	Note added that patient alert cards for apixaban are available via the SPC link.

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Tayside Area Formulary (TAF) Updates - August 2015

TAF Section	Drug(s)/Topic	Changes
02.12	Statins	Fluvastatin added to formulary and Cardiology specialist formulary list for prescribing by GPs for patients who cannot tolerate atorvastatin, simvastatin, or rosuvastatin, under the direction of the Cardiovascular risk clinic (Amber traffic light). Guidance on Aggressive lipid lowering in Acute Coronary Syndrome updated to reflect atorvastatin as formulary first choice statin. Simvastatin changed from second choice to standard formulary.
02.12	Ezetimibe	Tayside Algorithm A - Ezetimibe plus a statin and Tayside Algorithm B - Ezetimibe without a statin updated.
Chapter 3	Respiratory system	Link to NHS Tayside Respiratory MCN Adult Asthma Inhaled Medicine Chart updated.
03.01.02	Antimuscarinic bronchodilators - Asthma	Tiotropium (Spiriva® Respimat®) solution for inhalation added to formulary and Respiratory specialist formulary list for prescribing by GPs as add-on option for adult patients with asthma who remain symptomatic at BTS step 4, under the direction of the Respiratory / Asthma clinic (Amber traffic light). See SMC advice on page 6.
03.02	Single agent corticosteroids	Budesonide dry powder for inhalation changed from second choice to standard formulary. Beclometasone as Qvar® and Clenil Modulite® changed from first choice inhaled single agent corticosteroids to first choice MDI at Step 2.
03.02	Compound preparations - asthma	Fostair®, Flutiform®, and Seretide Accuhaler® now all equal formulary choices for asthma at Steps 3 or 4. Flutiform® and Seretide Accuhaler® now equal formulary choices for asthma at Step 5 as per updated NHS Tayside Respiratory MCN Adult Asthma Inhaled Medicine Chart .
04.10.02	Nicotine dependence	Tayside Guidance for Smoking Cessation reviewed and updated. Guidance is linked to from formulary entries for NRT and varenicline (Champix®▼). Information on drug interactions when stopping smoking added to prescribing notes.
05.01.02.01	Cephalosporins	Ceftobiprole concentrate for solution for infusion (Zevtera®▼) added to formulary (Hospital Only) for use only in accordance with Alert Antibiotics guidelines . See SMC advice on page 3.
05.01.05	Macrolides	Postoperative ileus indication [off-label] (Hospital Only) added to erythromycin formulary entry as per General Surgery specialist formulary list .
05.01.08	Sulphonamides and trimethoprim	Co-trimoxazole for preventing biliary stent occlusion [off-label] for prescribing by GPs under the direction of a Consultant Surgeon added as per General Surgery specialist formulary list .
05.02.01	Triazole antifungals	Posaconazole concentrate for solution for infusion (Noxafil®) added to formulary (Hospital Only) for use in haematology patients for prophylaxis if oral route unavailable. See SMC advice on page 4.
05.03.03.02	Chronic hepatitis C	Ombitasvir/paritaprevir/ritonavir (Viekirax®▼) and dasabuvir (Exviera®▼) added to formulary (Hospital Only) and Gastroenterology specialist formulary list for treatment of chronic hepatitis C in adult patients.
06.06.02	Denosumab	Note added that patient reminder cards regarding osteonecrosis of the jaw for denosumab (Prolia®) for osteoporosis and denosumab (Xgeva®) (non-formulary) are now available via the SPC link. See page 2 for further information.
08.03.04.01	Breast cancer	Fulvestrant now non-formulary.
09.05.01.03	Magnesium	Magnesium aspartate (Magnaspartate®) added as formulary (Green traffic light) for the treatment and prevention of magnesium deficiency as diagnosed by a doctor. See SMC advice on page 3.
10.01.01	Ibuprofen	Information on new contra-indications at higher dosage added to formulary entry and link to Drug Safety Update article, June 2015 (High-dose ibuprofen (≥ 2400mg/day): small increase in cardiovascular risk added. See page 2 for further information.

SMC Briefing Notes: [July](#) | [August](#)

[Forthcoming SMC Advice](#)

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.
[CLICK HERE](#) for access to the Medicines Governance section of the Pharmacy Staffnet site.

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

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