



Special Points of Interest for Primary Care

SMC Advice - December:

- Anakinra (Kineret®)
- Atomoxetine (Stattera®)
- Ceritinib (Zykadia®)
- Co-careldopa (Duodopa®)
- Denosumab (Xgeva®)
- Efavirenz (Sustiva®)
- Gefitinib (Iressa®)
- Glatiramer acetate (Copaxone®)
- Ivermectin 10mg/g cream (Soolantra®)
- Lenalidomide (Revlimid®)
- Naloxegol (Moventig®)

SMC Advice - January:

- Albiglutide (Eperzan®)
- Dulaglutide (Trulicity®)
- Netupitant/palonosetron (Akynzeo®)
- Sorafenib (Nexavar®)
- Tolvaptan (Jinarc®)
- Ustekinumab (Stelara®)

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Drug Safety Updates

Please follow link - [Drug Safety Update Download - January 2016](#)



Prescribing Changes

Primary Care Prescriptions

For several years primary care prescriptions have been processed at Practitioner Services (Part of NSS National Services Scotland, and responsible for the processing of GP and non-Medical Prescriptions dispensed through Community Pharmacy) by scanning technology. A trend has been noted nationally of increasing numbers of prescriptions where the scanned signature cannot be read by the technology. As a result all prescribers are asked to write and sign prescriptions in black ink only.

Levodopa/Carbidopa/Entacapone Combination Tablets

The combination tablet for Parkinson's which contains levodopa, carbidopa, and entacapone is now available as generic preparations. This combination medicine was previously only available as the branded product Stalevo®. The generic preparations currently available are branded generics (Stanek®, Sastravi®), however generic prescribing with the constituents specified in the order - levodopa/carbidopa/entacapone with the relevant strengths specified is preferred where possible. This allows supply of the most cost-effective product and the one that is readily available at the point of dispensing.

In the in-patient setting, the TPAR does not have enough space to prescribe this product generically as 'co-careldopa with entacapone' or as 'levodopa/carbidopa/entacapone' therefore it has been agreed that this can be prescribed by brand name. The hospital pharmacy service will substitute the most cost-effective brand irrespective of which one is prescribed. Pharmacists and pharmacy technicians will endorse TPARs with the brand supplied, however prescribers should be aware that they may be asked to clarify prescriptions when pharmacy staff are not available.

In primary care it is likely that this combination medicine will be prescribed generically. Clinicians undertaking medicines reconciliation on admission should be aware of the possible confusion with other Parkinson's medicines.

There is lack of clarity between BNF 70 and the manufacturers' Summary of Product Characteristics on the order in which the constituents of this combination medicine are listed. For clarity, it is recommended that the TPAR states the constituents in the order levodopa/carbidopa/entacapone. For example Stanek® 50/12.5/200 contains 50mg levodopa, 12.5mg carbidopa, 200mg entacapone.

Update on Shared Care Agreements

Tayside Area Drug & Therapeutics committee have clarified when a Shared Care Agreement (SCA) is required.

SCAs are established between secondary and primary care prior to the transfer of prescribing when treatment is long-term and specialist monitoring is required at predetermined intervals.

When no monitoring is required, a local protocol should be written where a new, rarely prescribed or unlicensed medicine is being recommended.

If the medicine is well established, prescribed within the licensed indication and requires no monitoring, then neither document is required.

Following a review of the Shared Care Agreements listed below, it has been agreed that SCAs are no longer required for:

- Dornase Alfa
- Nebulised Colistimethate Sodium (Promixin)
- Tobramycin (Paediatrics and Adult)
- Tacrolimus Ointment



Prescribing Changes

Prescribing & Use of Biosimilar Infliximab

NHS Tayside are endorsing the use of biosimilar infliximab to provide safe and clinically effective treatment to ensure the most cost effective use of available resources. Please see [Tayside Prescriber No. 141](#) for further information on use of biosimilar medicines in Tayside.

The following actions are to be implemented:

- The biosimilar brand Remsima[®]▼ to be included as first choice in the Tayside Area Formulary for new patients who meet the clinical criteria for infliximab
- All new patients are to be commenced on the Remsima[®]▼ brand from December 2015.
- All existing patients are to be reviewed at their next clinical appointment by December 2016 with a view to switching to the Remsima[®]▼ brand. The outcome of this review should be clearly documented in the patient record.

A patient screening sheet, patient alert card and safety sheet for Remsima[®]▼ are available via [Summary of Product Characteristics](#).

Actions for NHS Tayside staff

- Prescribers – all prescriptions for infliximab must specify the brand name, either Remsima[®]▼ or Remicade[®]. A prescription which states infliximab is not sufficient to ensure that the correct preparation is supplied or administered.
- Pharmacy staff – an order or prescription for infliximab should not be processed unless the brand name is stated or has been confirmed by the clinical area making the request.
- Nursing staff – infliximab should not be administered to a patient unless the brand name has been clearly specified on the prescription.

Warfarin 0.5mg tablets

The prescription of 0.5mg strength of warfarin is not recommended in secondary care, in NHS Tayside. Warfarin 0.5mg tablets have not been stocked in secondary care for many years as a result of an incident where a patient overdosed by inadvertently taking 5mg daily instead of the recommended 0.5mg dose.

The NHS Tayside Medicines Advisory Group (MAG) & the anticoagulant service, understand that there may be a very small cohort of patients in Tayside where the GP may find it preferable to use 0.5mg tablets. This could be to stabilise a patient who requires very low doses of warfarin and/or when a patient requires a fixed dose of warfarin that may include a 0.5mg tablet rather than alternating doses (the latter must only be used for patients where this is a safety issue). For licensed indications it may be preferable to use an alternative anticoagulant such as rivaroxaban or apixaban for such patients.

In conclusion, MAG does not support the complete withdrawal of 0.5mg warfarin tablets from Tayside. However, warfarin 0.5mg tablets should be prescribed with caution, fully discussing with the patient the potential for error in mistaking this for the 5mg strength tablet. Clinicians should also be aware that the 'warfarin monitoring' software dosing record may not fully reflect the actual daily regimen the patient is using. In these circumstances the true daily regimen will be fully documented in the patients dosing record book.



Tayside Area Formulary (Adult)

The [Tayside Area Formulary](#) is an adult formulary, for use in both the acute and primary care settings, and is hosted on the netFormulary platform. There have been a few incidents where prescribers have thought it also applies to children. This is not the case. To avoid any confusion the link to the BNF for children (BNFC) from individual drug entries of the Tayside Area formulary has been removed.

A link to [BNFC](#) is available from the [Paediatric Medical & Surgical Services website](#), [Neonatal Services website](#) and [Pharmacy website](#) (accessible via our websites from home page of staffnet). An Athens login may be required.

Tayside Area Formulary - User Survey

A short survey has been developed for the Tayside Area Formulary. The survey is intended for healthcare professionals within NHS Tayside who use or may use the formulary. It aims to explore the awareness of the formulary website or app, and users opinions on the usability of the formulary website or app.

A link to the survey has been emailed out to healthcare professionals across Tayside that currently receive emails with Tayside Prescriber bulletins from the Prescribing Support Unit. The survey can also be accessed from the following link:

<https://www.surveymonkey.co.uk/r/Formularysurvey>

The survey only takes a few minutes to complete and closes at 12 noon on Monday 29th February.

The Tayside Area Formulary app has recently been updated to improve the layout and functions. It is available by searching 'netformulary' from the App Store or Google play.

The Tayside Area Formulary website is accessible from the 'Formulary' tab on the top menu bar on Staffnet or by using the web address:

<http://www.taysideformulary.scot.nhs.uk/>

Thank you in anticipation of your help in completing the survey.

SMC Advice issued in November 2015 (publication date December 2015) SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Anakinra 100mg solution for injection in a pre-filled syringe (Kineret®) SMC No. 1116/15 Non-submission Not Recommended	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above, including: • Neonatal-Onset Multisystem inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Muckle-Wells Syndrome (MWS) • Familial Cold Autoinflammatory Syndrome (FCAS)	Not Recommended	SMC advice
Atomoxetine oral solution 4mg/mL (Strattera®) SMC No. 1107/15 Abbreviated Submission Accepted Restricted	Treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD. <u>SMC Restriction:</u> to use in patients who are unable to swallow capsules.	Formulary Amber - can be prescribed by General Practice under direction of a specialist	SMC advice SPC link

* '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
<p>Ceritinib 150mg hard capsules (Zykadia®)</p> <p>SMC No. 1097/15 Full Submission Accepted with PAS</p>	<p>Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.</p>	<p>Non-Formulary Pending local decision</p>	<p>SMC advice SPC link</p>
<p>Co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®)</p> <p>SMC No. 316/06 Resubmission considered under the orphan process Not Recommended</p>	<p>Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.</p>	<p>Not Recommended</p>	<p>SMC advice</p>
<p>Denosumab 120mg solution for injection (Xgeva®)</p> <p>SMC No. 1119/15 Non-submission Not Recommended</p>	<p>Adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity</p>	<p>Not Recommended</p>	<p>SMC advice</p>
<p>Efavirenz 50mg, 100mg and 200mg hard capsules and 600mg film-coated tablets (Sustiva®)</p> <p>SMC No. 1125/15 Abbreviated Submission Accepted</p>	<p>Antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3.5kg.</p>	<p>Formulary Hospital Use Only (Paediatrics/HIV clinic)</p>	<p>SMC advice Links to: Efavirenz hard capsules and Efavirenz film coated tablets</p>
<p>Gefitinib 250mg film-coated tablets (Iressa®)</p> <p>SMC No. 615/10 2nd Resubmission Accepted Restricted with PAS</p>	<p>Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).</p> <p>SMC Restriction: in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy.</p>	<p>Non-Formulary Pending local decision</p>	<p>SMC advice SPC link</p>
<p>Glatiramer acetate 40mg/mL solution for injection prefilled syringes (Copaxone®)</p> <p>SMC No. 1108/15 Abbreviated Submission Accepted</p>	<p>Treatment of relapsing forms of multiple sclerosis (MS).</p>	<p>Formulary Hospital Use Only (Neurology)</p>	<p>SMC advice SPC link</p>
<p>Ivermectin 10mg/g cream (Soolantra®)</p> <p>SMC No. 1104/15 Full Submission Accepted Restricted</p>	<p>Topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.</p> <p>SMC Restriction: the treatment of moderate to severe inflammatory lesions of rosacea where a topical treatment is considered appropriate.</p>	<p>Formulary</p>	<p>SMC advice SPC link</p> <p><i>The acne & rosacea formulary section is under review.</i></p>

* '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
<p>Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®)</p> <p>SMC No. 1096/15 Full submission considered under the orphan process Accepted Restricted</p>	<p>Treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.</p> <p><u>SMC Restriction:</u> for use in patients unsuitable for thalidomide-containing regimens</p>	<p>Non-Formulary Pending local decision</p>	<p>SMC advice SPC links: 2.5mg 5mg 7.5mg 10mg 15mg 20mg 25mg</p>
<p>Naloxegol 12.5mg and 25mg film-coated tablets (Moventig®)</p> <p>SMC No. 1106/15 Full Submission Accepted</p>	<p>Treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s).</p>	<p>Formulary Amber - can be prescribed by General Practice under direction of a specialist</p>	<p>SMC advice SPC link Local treatment protocol</p>

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
<p>Albiglutide 30mg and 50mg pre-filled pen (Eperzan®)</p> <p>SMC No. 1024/15 Deferred Advice Accepted Restricted with PAS</p>	<p>Treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.</p> <p><u>SMC Restriction:</u> an alternative once weekly glucagon-like peptide-1 (GLP-1) agonist for use in combination with oral anti-diabetic agents as a third-line pre-insulin treatment option.</p>	<p>Non-Formulary Pending local Agreement</p>	<p>SMC advice SPC links: 30mg 50mg</p>
<p>Dulaglutide 0.75mg and 1.5mg solution for injection in pre-filled pen (Trulicity®)</p> <p>SMC No. 1110/15 Full Submission Accepted Restricted</p>	<p>In adults with type 2 diabetes mellitus to improve glycaemic control as add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.</p> <p><u>SMC Restriction:</u> as part of a triple therapy in patients with inadequate glycaemic control on two oral anti-diabetic drugs, as an alternative glucagon-like peptide 1 (GLP-1) agonist option.</p>	<p>Non-Formulary Pending local Agreement</p>	<p>SMC advice SPC link</p>
<p>Netupitant/palonosetron 300mg/0.5mg, hard capsule (Akynzeo®)</p> <p>SMC No. 1109/15 Full Submission Accepted Restricted with PAS</p>	<p>In adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.</p> <p><u>SMC Restriction:</u> prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.</p>	<p>Non-Formulary Pending local Agreement</p>	<p>SMC advice SPC link</p>

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Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Sorafenib 200mg film-coated tablets (Nexavar®) SMC No. 482/08 2nd Resubmission under the end of life and orphan process Accepted Restricted with PAS	The treatment of hepatocellular carcinoma. <u>SMC Restriction:</u> in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies.	Non-Formulary Pending local Agreement	SMC advice SPC link
Tolvaptan 15mg, 30mg, 45mg, 60mg and 90mg tablets (Jinarc®) SMC No. 1114/15 Full Submission under the orphan process Accepted with PAS	To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.	Non-Formulary Pending local Agreement	SMC advice SPC links: 15mg 30mg 45mg 60mg 90mg
Ustekinumab 45mg solution for injection and prefilled syringe (Stelara®) SMC No. 1115/15 Abbreviated Submission Accepted Restricted	Treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. <u>SMC Restriction:</u> continued treatment should be restricted to patients who achieve at least 75% improvement in their Psoriasis Area and Severity Index (PASI 75) within 16 weeks.	Formulary Hospital Use Only (Paediatric Dermatology Clinic)	SMC advice SPC links: solution for injection and prefilled syringe

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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 \(including Individual Patient Treatment Requests\)](#).

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Abiraterone acetate 250mg tablets (Zytiga®) SMC No. 873/13	With prednisone or prednisolone for treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Formulary Hospital Use only (Oncology)	
Bevacizumab, 25mg/ml, concentrate for solution for infusion (Avastin®) SMC No. 806/12	In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. <u>SMC restriction:</u> In patients with FIGO stage IV disease	Formulary Hospital use only (Oncology)	



Tayside Area Formulary (TAF) Updates - Dec/Jan 2015/16

Medicines within the Tayside Area Formulary are intended to guide choice on a rational selection of medicines for **adults** which have been included on the basis of clinical efficacy, safety, patient acceptability and cost-effectiveness.

TAF Section	Drug(s)/Topic	Changes
01.05.03	Cytokine modulators	Infliximab (Remicade®) now non-formulary. Biosimilar infliximab (Remsima® ▼) now formulary and added to Gastroenterology specialist formulary list . Addition of statement on use of biosimilars added.
01.06.07	Other drugs used in constipation	Naloxegol (Moventig® ▼) added to formulary and Acute Pain , Chronic Pain , Palliative Care , and Oncology & Haematology non-chemo drugs Specialist formulary lists as GPs may prescribe under specialist direction (Amber traffic light) for opioid-induced constipation in adult patients who have had an inadequate response to at least 4 days treatment with at least one class of laxative. See SMC advice on Page 5. Link to Naloxegol local new medicine treatment protocol added.
04.04	ADHD in adults	Atomoxetine oral solution (Strattera®) added to formulary for use in patients who are unable to swallow capsules. See SMC advice on Page 3. Dexamfetamine [off-label], lisdexamfetamine, and methylphenidate [off-label] added as formulary for treatment of ADHD in adults in accordance with the local Adult ADHD Treatment Shared Care Agreement .
04.09.01	Levodopa	Brand names removed from co-beneldopa, co-careldopa, and co-careldopa with entacapone drug entries as generic preparations available. Link to documents with Preparations of co-beneldopa and co-careldopa currently available and on formulary and Preparations of co-careldopa with entacapone currently available and on formulary updated .
06.01.02.06	Sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors)	Empagliflozin (Jardiance® ▼) now first choice SGLT2 inhibitor. Empagliflozin in combination with insulin added to Endocrinology specialist formulary list (Amber traffic light) (GPs may prescribe under the direction of the Diabetes team). Empagliflozin and metformin (Synjardy® ▼) now formulary. Dapagliflozin ▼ now second choice SGLT2 inhibitor and canagliflozin ▼ and canagliflozin and metformin (Vokanamet® ▼) now non-formulary.
07.03.05	Emergency contraception - hormonal methods	Link to statement from the Faculty of Sexual and Reproductive Healthcare (FSRH) on quick-starting hormonal contraception after use of ulipristal acetate (ellaOne®) added. As FSRH advice includes off-label use of ulipristal acetate, further information has been added to the ulipristal acetate formulary entry.
10.01.03	Cytokine modulators	Infliximab (Remicade®) now non-formulary. Biosimilar infliximab (Remsima® ▼) now formulary and added to the Rheumatology specialist formulary list . Addition of statement on use of biosimilars added.
13.05.03	Cytokine modulators	Infliximab (Remicade®) now non-formulary. Biosimilar infliximab (Remsima® ▼) now formulary and added to the Dermatology specialist formulary list . Addition of statement on use of biosimilars added.
13.07	Preparations for warts and calluses	Salactol® paint replaced with Salatac® gel as it does not require a dressing/plaster.

SMC Briefing Note: [January 2016](#)

[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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