



Guidelines and Protocols

Testosterone: Long Term Treatment for Male Hypogonadism

A [local treatment protocol](#) has been developed by Endocrine specialists providing useful information on available testosterone preparations, including contra-indications, cautions, side-effects and monitoring to be undertaken by secondary and primary care in NHS Tayside for the long term treatment of male hypogonadism. A link to this protocol is available from [testosterone entries](#) and [Endocrine Specialist List](#) in the Tayside Area Formulary.

Monitoring of testosterone in primary care can be claimed for under the Near Patient Testing Enhanced Service Specification and administration of IM injections under the Minor Surgery Enhanced Service Specification.



Prescribing Changes and Formulary Updates

Smoking cessation pathways and formulary update

NHS Tayside Smoke Free Service have published patient pathways and prescribing guidance to support smoking cessation. The pathways and guidance were developed by Public Health, along with input and support from Mental Health and the Medicines Advisory Group (MAG).

Please see the links below to the pathways and guidance which collectively cover primary and secondary care across Tayside:

- [Primary Care Smoking Cessation Patient Pathway](#)
- [NHS Tayside Primary Care Smoking Cessation Prescribing Guidance Varenicline & NRT](#)
- [Smokers' Inpatient Pathway](#)
- [Mental Health & Learning Disability Smokers' Inpatient Pathway](#)
- [NHS Tayside Inpatient Nicotine Replacement Therapy Prescribing Guidance](#)

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The Tayside Area Formulary [section 04.10.02](#) on nicotine dependence has been updated:

- **Varenicline with weekly behavioural/motivational support is first line for a smoking quit attempt in primary care**
- **Nicotinell® TTS patches are now the first choice NRT preparation (most cost-effective)**
- **Nicorette® Inhalator and NiQuitin® Minis are alternative NRT preparations**
- **NRT is recommended for hospital inpatients for those motivated to stop smoking or for nicotine withdrawal management**
- **NRT is an option for primary care patients who are unsuitable for varenicline**

Formulary Medicines moved to Non-formulary Medicines

The Tayside Area Formulary includes over one thousand formulary items. Approximately 50% are indicated for general prescribing (green traffic light); 25% GP under the direction of a specialist (amber traffic light) and 25% Hospital Only (red traffic light). The formulary is constantly being reviewed and medicines that are prescribed infrequently may be moved to non-formulary. As part of the rapid formulary review several medicines have been moved to non-formulary if it was felt that the use was low or the drug was unlikely to be initiated in new patients. Examples include: beclometasone inhaler (Clenil Modulite®), gabapentin & venlafaxine (migraine prophylaxis (off-label)), amitriptyline (antidepressant) and lurasidone (schizophrenia).

All formulary medicines that have moved to non-formulary will include a standard sentence : 'May be continued in existing patients as appropriate.'

Existing patients who were prescribed a formulary medicine for its approved indication that has been changed to a non-formulary medicine can therefore continue on this medicine without requiring a non-formulary request form.



Drug Safety Updates

Please follow links to Drug Safety Updates for: [June 2017](#) | [July 2017](#)



Information Technology

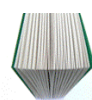
New BNF & BNFC App

[Click Here](#) for detailed information about the new BNF & BNFC app.

A replacement app for BNF and BNFC is now available. It is structured like the revised BNF on MedicinesComplete rather than the 'legacy' book chapter format, and is one app covering both BNF and BNFC. Another major change is that the app is available from iTunes and PlayStore to anyone with an account on these services, and does not require OpenAthens authentication as before.

The new App will eventually replace the NICE BNF App. To begin with, both Apps will be available in order to allow users time to download and familiarise themselves with the new BNF & BNFC App. Both Apps will continue to be updated monthly with BNF content, so you can be confident they contain the latest information.

It is expected that the NICE BNF App will be retired in the next few months, and updates to this version of the App will cease.



Specialist Formulary List Updates

Headache Specialist Formulary List

A [Headache Specialist Formulary List](#) has been developed which includes treatments for prevention of migraine. It includes treatments which may be prescribed by GPs and more specialist treatments prescribed by Hospital Specialists.

The migraine prophylaxis section of the formulary has been updated following a review over the last year, reflecting the most up to date evidence.

Updates include:

- Topiramate (Amber traffic light) now listed as 2nd choice for migraine prophylaxis (amitriptyline [off-label] and propranolol remain 1st choice options (both Green traffic light))
- Candesartan [off-label] (Amber traffic light) has been added as a 3rd choice
- Sodium valproate [off-label] (Amber traffic light) is now listed as a 4th choice
- Gabapentin [off-label] and venlafaxine [off-label] are now non-formulary for migraine prophylaxis

SIGN guidance on migraine is currently in development, and once published, a full review of the antimigraine drugs section of the formulary (including treatment of acute migraine attack) will be undertaken.

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Alectinib hydrochloride, 150mg hard capsules (Alecensa®) SMC No: (1257/17) Absence of submission Not recommended	As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib	Not available as not recommended for use in NHS Scotland	SMC Link
Belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) SMC No. (775/12) Resubmission Accepted restricted	Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy Restriction: patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥ 10 .	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	SMC Link SPC Link
Idebenone, 150mg film-coated tablets (Raxone®) SMC No. (1226/17) Full submission assessed under ultra-orphan medicine process Accepted restricted	Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). Restriction: to patients with LHON who are not yet blind i.e. they do not meet the UK criteria to be registered as severely sight impaired.	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	SMC Link SPC Link
Liraglutide, 6mg/mL solution for injection in pre-filled pen (Saxenda®) SMC No: (1247/17) In the absence of submission Not recommended	As an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of • $\geq 30\text{kg/m}^2$ (obese), or • $\geq 27\text{kg/m}^2$ to $< 30\text{kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.	Not available as not recommended for use in NHS Scotland	SMC Link
Micronised progesterone, vaginal capsules 200mg (Utrogestan®) SMC No (935/13) Full submission Accepted	In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by Sep 2017	SMC Link SPC Link
Talimogene laherparepvec, 106 and 108 plaque forming units (PFU)/mL solution for injection (Imlygic®) SMC No: (1248/17) Absence of submission Not recommended	Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.	Not available as not recommended for use in NHS Scotland	SMC Link

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Adalimumab, 40mg/0.4mL pre-filled syringe (Humira®) and pre-filled pen adalimumab, 40mg/0.8mL vial for paediatric use (Humira®) SMC No. (1243/17) Abbreviated submission Accepted	Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy	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	SMC Link SPC Links: 40mg/0.4mL 40mg/0.8mL

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

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Aprepitant, 80mg, 125mg hard capsules and 125mg powder for oral suspension (Emend®) SMC No (1241/17) Full submission Accepted	As part of combination therapy, for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in infants, toddlers and children from the age of six months to less than 12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules).	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	SMC Link SPC Links: 80mg, 125mg hard capsules 125mg powder
Budesonide/formoterol, 100 micrograms/6 micrograms and 200 micrograms/6 micrograms inhalation powder (Symbicort® SMART®) SMC No. (1244/17) Abbreviated submission Accepted	The regular treatment of asthma where use of a combination inhaled corticosteroid and a long-acting β_2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" short-acting β_2 adrenoceptor agonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists. This advice relates to the extension of the license for Symbicort maintenance and reliever therapy (SMART®) to adolescents aged 12 to <18 years.	Available in line with National Guidance Initiation through Hospital respiratory Clinic only	SMC Link SPC Links: 100 micrograms/6 micrograms 200 micrograms/6 micrograms
Buprenorphine, 2mg, 8mg oral lyophilisate (Espranor®) SMC No (1245/17) Abbreviated submission Accepted restricted	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction. <u>Restriction:</u> to patients in whom methadone is not suitable.	Available in line with National guidance Restricted to use in TSMS Formulary - specialist prescribing	SMC Link SPC Links: 2mg 8mg
Cabozantinib, 20mg, 40mg and 60mg film-coated tablets (Cabometyx®) SMC No. (1234/17) Full submission assessed under the end of life process Accepted	For the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by Sep 2017	SMC Link SPC Link
Deferasirox, 90mg, 180mg and 360mg film-coated tablets (Exjade®) SMC No (1246/17) Abbreviated submission Accepted restricted	<ul style="list-style-type: none"> • Treatment of chronic iron overload due to frequent blood transfusions ($\geq 7\text{mL/kg/month}$ of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. • Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups: <ul style="list-style-type: none"> - in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions ($\geq 7\text{mL/kg/month}$ of packed red blood cells) aged 2 to 5 years, - in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions ($< 7\text{mL/kg/month}$ of packed red blood cells) aged 2 years and older, - in adult and paediatric patients with other anaemias aged 2 years and older <u>Restriction:</u> deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07 - accepted for restricted use within NHS Scotland for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions. It is not recommended for patients with myelodysplastic syndromes).	Available in line with National Guidance	SMC Link SPC Link
Ibrutinib, 140mg hard capsules (Imbruvica®) SMC No: (1258/17) Absence of submission Not recommended	In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy	Not available as not recommended for use in NHS Scotland	SMC Link

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No. (1188/16) Resubmission assessed under the end of life and orphan medicine process Accepted	As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by Sep 2017	SMC Link SPC Link
Obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva®) SMC No (1232/17) Full submission assessed under the orphan medicine process Accepted	Primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid.	Available in line with National Guidance Formulary - under the direction of the liver clinic	SMC Link SPC Link
Pertuzumab, 30mg/mL concentrate for solution for infusion (Perjeta®) SMC No. (897/13) Second resubmission assessed under the orphan medicine process Not recommended	For use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease	Not available as not recommended for use in NHS Scotland	SMC Link
Safinamide, 50mg/100mg film-coated tablets (Xadago®) SMC No. (1259/17) Absence of submission Not recommended	Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients	Not available as not recommended for use in NHS Scotland	SMC Link

Updates from previous SMC Advice

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

Botulinum toxin A, 50 Allergan units, 100 Allergan units, 200 Allergan units, powder for solution for injection (Botox®) SMC No. 692/11 Resubmission Accepted Restricted	Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). SMC Restriction: use in adults with chronic migraine whose condition has failed to respond to ≥3 prior oral prophylactic treatments, where medication overuse has been appropriately managed.	Available in line with local guidance for prescribing Formulary - Hospital Only	SMC Advice SPC Links: 50 units 100 units 200 units
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Other Formulary Updates June/July 2017

Links to formulary updates for SMC accepted medicines* are included in the SMC Advice tables above and on the previous pages.

Other formulary updates not included in the sections on 'Prescribing Changes and Formulary Updates' or 'Specialist Formulary Lists' are detailed below.

Further detail on formulary changes can be found by clicking on the Tracked Changes paw print button on the relevant drug entries within the [Formulary](#).

Formulary Section	Drug(s)/Topic	Changes
Chapter 3	Useful links	Link to NHS Tayside Inhaled Corticosteroid Withdrawal Protocol in COPD added.
03.06	Oxygen	Link added to NHS Tayside Oxygen Guidelines (Staffnet site) which includes links to oxygen policy and several documents which replace previous guidance within the formulary on oxygen.



Other Formulary Updates - June/July 2017

TAF Section	Drug(s)/Topic	Changes
04.01.03	Anxiety disorders	Pregabalin added to formulary (Amber traffic light) and Mental Health Specialist formulary list . GPs may prescribe under specialist direction for generalised anxiety disorder where SSRIs or venlafaxine are ineffective, poorly tolerated, or considered clinically inappropriate. Link to NICE CG113 Generalised anxiety disorder and panic disorder in adults: management, January 2011 added.
04.07.04.02	Prophylaxis of migraine	See article on page 2. Flunarizine (unlicensed) added to Headache Specialist Formulary List (Hospital Only) for prescribing by Neurologists for prophylaxis of frequent, severe migraine when other treatment options have failed. See Local Treatment Protocol for further information.
06.06.02	Bisphosphonates and other drugs affecting bone metabolism	Link to NHS Tayside Bisphosphonate Holiday Guidance removed as this has been superseded by advice within Tayside MFE Osteoporosis Treatment Algorithm .
13.06.01	Topical retinoids and related preparations for acne	Isotretinoin (Isotrex [®]) gel now non-formulary as discontinued by the manufacturer. Adapalene cream 0.1% or gel 0.1% remains in this section as an alternative.

* 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.

Forthcoming SMC Advice

Local implementation of SMC recommendations is taken forward by the Tayside Prescribing Support Unit (PSU). This bulletin is based on evidence available to Tayside PSU 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. Please direct any queries to:

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