



## Tayside DTC Supplement No 140 – July / August 2014

Produced by NHS Tayside Drug and Therapeutics Committee Medicines Advisory Group (MAG)

### Special points of interest for Primary Care

#### SMC advice - July:

- Alemtuzumab (Lemtrada<sup>®</sup>)
- Beclometasone / formoterol (Fostair<sup>®</sup>)
- Botulinum toxin type A (Botox<sup>®</sup>)
- Botulinum toxin type A (Botox<sup>®</sup>)
- Certolizumab pegol (Cimzia<sup>®</sup>)
- Dapagliflozin (Forxiga<sup>®</sup>)
- Dapoxetine hydrochloride (Priligy<sup>®</sup>)
- Pomalidomide (Imnovid<sup>®</sup>)
- Rituximab (Mabthera<sup>®</sup>)

#### SMC advice - August:

- Colestilan (BindRen<sup>®</sup>)
- Dapagliflozin plus metformin (Xigduo<sup>®</sup>)
- Lubiprostone (Amitiza<sup>®</sup>)
- Ocriplasmin (Jetrea<sup>®</sup>)
- Olodaterol (Striverdi<sup>®</sup> Respimat<sup>®</sup>)
- Racecadotril (Hidrasec Infants<sup>®</sup>, Hidrasec Children<sup>®</sup>)
- Tocilizumab (RoActemra<sup>®</sup>)
- Umeclidinium/vilanterol (Anoro<sup>®</sup>)

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## Prescribing changes

### New website for the Tayside Area Formulary (TAF) - now available

The Tayside Area Formulary (TAF) is now available on the netFormulary platform. It can be accessed from the 'Formulary' tab on [Staffnet](#); online at [www.taysideformulary.scot.nhs.uk](http://www.taysideformulary.scot.nhs.uk); or by downloading the 'netFormulary' app (for Apple (iOS) or Android devices).

Feedback from users on the new website has been very positive and the demonstration stands have been very helpful in raising awareness of the formulary among healthcare professionals.

There are 2 remaining dates at Ninewells Hospital where pharmacy staff will be available to provide demonstrations and answer questions regarding the new TAF website and netFormulary app:

Venue	Dates
Ninewells Hospital - level 5 (outside Doctors' Mess) - 10am to 2pm	Tuesday 9 <sup>th</sup> & Wednesday 10 <sup>th</sup> September 2014

Users will require to familiarise themselves with the new TAF website and have a go at using the search function to find information. A useful summary of how to navigate the new site and app is available in a recent bulletin - [Tayside Prescriber Issue 134, August 2014](#). More detailed information is also available in the [User Guide for the website](#) and the [User Guide for the app](#) which are available from the [TAF home page](#).

The following points have been raised since the launch of the TAF website and the app which are useful for users to be aware of:

- **The Medusa (Injectable Medicines Guide) link from the TAF home page may not always be displayed** (work is continuing on this). Users may find an alternative link to Medusa by clicking on 'Pharmacy Website' in the useful links table on the TAF home page. A Medusa link is then listed under 'Useful links' on the right hand side of the Staffnet Pharmacy website. The Medusa link will only be available to NHS Tayside users.
- **Any users of the app experiencing issues with performance of the app should first uninstall their app, then re-install and update it.** If any users experience issues with the app after doing this, please use the [feedback facility](#) on the TAF website.
- **All linked files in the app can now be downloaded within the app.** Initially not all links were working within the Tayside netFormulary app on both iOS and android devices and users of the app were advised to download only linked files from Chapters 5 and 22. However, this issue has now been resolved.

**NB. Remember to update app data over Wi-Fi at the beginning of each month.**

Any feedback/comments or requests to organise further demos or presentations can be made by using the [feedback facility](#) on the TAF website.



## Drug Safety Updates

Please follow links - [Volume 7, Issue 12, July 2014](#)

[Volume 8, Issue 1, August 2014](#)



## Drug Safety Updates - continued....

### E-learning modules on adverse drug reactions

NHS Education for Scotland and Yellow Card Centre Scotland have jointly published six [e-learning modules on adverse drug reactions](#), which introduce the healthcare professional to basic characteristics of adverse reactions and lay down the principles of recognising and avoiding them. The final module covers pharmacovigilance.

These e-learning modules are written for doctors, nurses and pharmacists - they are especially suited for those in foundation training programmes and those requiring an update in this area for their continuing professional development. The modules will ensure that all healthcare professionals attain a consistent standard of understanding on adverse drug reactions. Learners will also become more confident about when and how to report adverse drug reactions on Yellow Cards.

The e-learning modules are accessible from the [Adverse Drug Reactions](#) link on the home page of the [Tayside Area Formulary](#).

### Transdermal fentanyl patches & risk of accidental exposure

A recent European- wide review has highlighted the need for safe handling of transdermal fentanyl patches<sup>1</sup>. They can cause harm if the patch is transferred to another individual or swallowed or an inappropriate dose is given (see [Drug Safety Update Vol 2, issue 2, September 2008 - Fentanyl patch](#)).

There have been 3 yellow card reports to date describing accidental exposure of fentanyl patches, two of which involved children.

Prescribers are reminded to provide clear information on transdermal fentanyl patches to patients and caregivers regarding risk of accidental transfer and ingestion, and the need for appropriate disposal. [Click Here](#) for further information for health care professionals. [Guidance](#) for patients has also been produced.

Particular care should be taken in the presence of children who may touch, suck, chew or swallow a patch that has not been disposed of properly. Also, children have a lower threshold for fentanyl overdose than adults.

1. [Drug Safety Update vol 7, issue 12, July 2014, S1 - Fentanyl patch](#)



## Prescribing Changes

### Prescribing of orlistat in Tayside

The Tayside Adult Weight Management Service (AWMS) has undergone re-design and a new Adult Weight Management (AWM) pathway is now in place. Letters have been sent to general practitioners across Tayside informing them of the service and including a copy of the new pathway.

As part of the new AWM pathway, patients within the programme may be eligible for prescription of orlistat (Xenical®). To ensure appropriate and cost effective prescribing, it has been agreed that in Tayside orlistat should only be initiated on the recommendation of the AWM team. The [Tayside Area Formulary](#) has been updated to reflect this change and orlistat now has an Amber prescribing status (prescribed in general practice under the direction of a specialist).

Prescribing of orlistat will be by GPs on the recommendation of the AWMS. Patients will be fully supported and monitored during treatment to enable maximum benefit to be reached and adverse effects kept to a minimum.

A Tayside Prescriber on the Anti-Obesity Agent - Orlistat is being updated to incorporate the above changes.

When the AWM pathway is available as an intranet link, it will be available from the Tayside Area Formulary.

Medicine	Indication	Local recommendation category	Comments and useful links
Alemtuzumab, 12mg, concentrate for solution for infusion (Lemtrada®) (959/14) - Full submission	For adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.	<b>Non formulary— protocol pending</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>MS specialist list under development</i>
Beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler (MDI) 100 microgram / 6microgram (Fostair®) (976/14) - Abbreviated submission	Symptomatic treatment of patients with severe COPD (FEV <sub>1</sub> <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	<b>Formulary</b>  <b>1st line choice</b>  In patients unable to tolerate an MDI Seretide 500 Accuhaler® should be used.	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Symbicort® removed from formulary for COPD (new patients). Existing COPD patients should continue with Symbicort®.</i>
Botulinum toxin type A powder for solution for injection (BOTOX®) (931/13) - Full submission	The management of bladder dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency. <b>SMC restriction:</b> Patients who have failed appropriate oral treatment options.	<b>Hospital Only</b> <b>Urology Specialist List</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Restricted to use in patients who have failed standard oral treatments including mirabegron</i>
Botulinum toxin type A 50, 100 and 200 units (Botox) (986/14) - Non-submission	Focal lower limb spasticity, including the treatment of ankle disability due to lower limb spasticity associated with stroke in adults.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Certolizumab pegol, 200mg/mL, solution for injection in pre-filled syringe (Cimzia®) (973/14) - Full submission	In combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. <b>SMC restriction:</b> Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.	<b>Hospital Only</b> <b>Rheumatology Specialist List</b>  <b>1st line choice</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Non-formulary for Dermatology</i>
Dapagliflozin 5mg and 10mg film-coated tablet (Forxiga®) (799/12) - 2 <sup>nd</sup> Resubmission	In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. <b>SMC restriction:</b> in triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor.	<b>Formulary</b>  <b>Already on formulary for dual therapy with metformin &amp; Endocrine specialist list in combination with insulin</b>  <b>SMC not recommended for monotherapy</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Avoid if eGFR &lt; 60mL/min or with loop diuretics or ≥75yrs.</i>  <b>Alternative to canagliflozin.</b>
Dapoxetine hydrochloride 30mg and 60 mg film-coated tablets (Priligy) (987/14) - Non-submission	Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) (972/14) - Full submission	In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.	<b>Not recommended</b>	<a href="#">SMC advice</a>

\* '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
Rituximab 1400mg solution for subcutaneous injection (Mabthera®) (975/14) - Full submission	For non-Hodgkin's lymphoma (NHL) in adults: - previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy; - maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy; - treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.  <b>SMC restriction:</b> Subcutaneous rituximab is accepted for use in line with previous SMC advice for intravenous rituximab i.e. accepted within licensed indication as above except in the maintenance setting, where use is restricted to patients who have responded to induction therapy with rituximab plus chemotherapy.	<b>Hospital Only</b>  <b>Haematology</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>

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

## SMC Advice issued in July 2014 (publication date 11 August 2014)

SMC website: [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

Medicine	Indication	Local recommendation category	Comments and useful links
Colestilan 1g film-coated tablet, 2g and 3g granules sachet (BindRen®) (939/14) - Resubmission	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Dapagliflozin plus metformin 5mg/850mg and 5mg/1000mg film-coated tablets (Xigduo®) (983/14) - Abbreviated submission	In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: <ul style="list-style-type: none"> <li>in patients inadequately controlled on their maximally tolerated dose of metformin alone;</li> <li>in combination with other glucose-lowering medicinal products, including insulin, in patients inadequately controlled with metformin and these medicinal products;</li> <li>in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.</li> </ul> <b>SMC restriction:</b> to use in patients for whom a combination of dapagliflozin and metformin is an appropriate choice of therapy i.e. <ul style="list-style-type: none"> <li>when metformin alone does not provide adequate glycaemic control and a sulphonylurea is inappropriate.</li> <li>in combination with insulin, when insulin and metformin does not provide adequate control.</li> <li>in combination with a sulphonylurea, when a sulphonylurea and metformin does not provide adequate control.</li> </ul>	<b>Formulary</b>  Dual therapy or triple therapy with a sulphonylurea  Triple therapy with insulin ( <b>Endocrinology Specialist List</b> )	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <b>Avoid if eGFR &lt; 60mL/min or with loop diuretics or ≥75yrs</b>  <b>Alternative to canagliflozin.</b>  <b>Twice daily dosing—useful where compliance an issue and patients controlled on set doses</b>

Medicine	Indication	Local recommendation category	Comments and useful links
Lubiprostone, 24 micrograms soft capsules (Amitiza®) (977/14) - Full submission	The treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures (e.g. educational measures, physical activity) are inappropriate.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®) (892/13) - Resubmission	In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. <b>SMC restriction:</b> patients with vitreomacular traction plus macular hole, regardless of whether they have epiretinal membrane formation, and in patients with vitreomacular traction alone (no epiretinal membrane and no macular hole).	<b>Non-Formulary - absence of clinician demand</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®) (974/14) - Full submission	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants®, Hidrasec Children®) (818/12) - Resubmission	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 and when causal treatment is not possible. If causal treatment is possible racecadotril can be administered as a complementary treatment.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Tocilizumab, 162mg, solution for injection in pre-filled syringe (RoActemra®) (982/14) - Full submission	In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. Tocilizumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate. <b>SMC restriction:</b> tocilizumab is restricted to use in accordance with current eligibility and continuation rules for biologic therapies in rheumatoid arthritis.	<b>Hospital Only</b> <b>Rheumatology Specialist List</b>  <b>1st line in patients who can not tolerate a DMARD or in whom a DMARD is contraindicated</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Tocilizumab 162mg, subcutaneous injection, once weekly is the preferred option.</i> <i>The monthly iv infusion will be reserved for patients who can't tolerate the sc preparation</i>
Umeclidinium/vilanterol, 55/22 micrograms, inhalation powder (Anoro®) (978/14) - Full submission	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	<b>Not recommended</b>	<a href="#">SMC advice</a>

### Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Infliximab 100mg powder for intravenous infusion (Remicade®) (363/07) & (364/07) - Full submissions	Severe active Crohn's disease. Fistulising, active Crohn's disease.	<b>HOSPITAL ONLY</b> <b>Gastroenterology Specialist List</b>	<a href="#">NICE MTA 187</a> (May 2010)

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# Tayside Area Formulary (TAF) Updates - July 2014

TAF Section	Drug(s)/topic	Changes
<a href="#">01.05.03</a>	Infliximab (IBD)	Added to formulary and Gastroenterology specialist formulary list* as an alternative to adalimumab in patients with fistulating Crohn's disease or issues with compliance to weekly/fortnightly adalimumab therapy at home. In accordance with <a href="#">NICE MTA 187</a> . See also page 5.
<a href="#">03.02</a>	Corticosteroids	Beclometasone/formoterol (Fostair®) added to formulary as first choice combination ICS/LABA MDI in severe COPD. See page 3 for SMC advice. Seretide 500 Accuhaler® now first choice ICS/LABA DPI in severe COPD. Relvar Ellipta® now listed as second choice ICS/LABA in severe COPD as Symbicort® no longer formulary for COPD. Existing patients on Symbicort® for COPD should continue.  Budesonide Turbohaler and Fluticasone (Flixotide®) both for asthma now non-formulary. Budesonide Easyhaler® remains in formulary as second choice single agent corticosteroid.
<a href="#">04.05.01</a>	Orlistat	Prescribing status changed from Green to Amber. See page 2 for further information.
<a href="#">06.01.02.06</a>	Other antidiabetic drugs	Dapagliflozin (Forxiga®) for triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor – indication added to formulary. See SMC advice on page 3.  Dapagliflozin plus metformin 5mg/850mg and 5mg/1000mg film-coated tablets (Xigduo®) added to formulary and Endocrinology specialist formulary list* (triple therapy with insulin) as per SMC advice - see page 4.
<a href="#">07.04.02</a>	Urinary incontinence	Botulinum toxin type A powder for solution for injection (BOTOX®) for overactive bladder with symptoms of urinary incontinence, urgency and frequency in patients who have failed standard oral treatments including mirabegron - indication added to formulary and Urology specialist formulary list*. See SMC advice on page 3.
<a href="#">10.01.03</a>	Cytokine modulators	Certolizumab pegol solution for injection in pre-filled syringe (Cimzia®) now first choice for active PsA when response to at least 2 standard DMARDs (individually or in combination) has been inadequate (added to formulary and Rheumatology specialist formulary list*). See SMC advice - page 3.  Tocilizumab solution for injection in pre-filled syringe (RoActemra®) added as a new formulation to formulary and Rheumatology specialist formulary list*. See SMC advice - page 5.
<a href="#">12.01.01</a>	Locorten-Vioform® (flumetasone with clioquinol)	Changed to non-formulary with note added that it has been discontinued by manufacturer. (Will no longer be listed at all after 2 years or next Chapter 12 review).
<a href="#">15.02</a>	Pliaglis® (lidocaine 7% and tetracaine 7%)	Added as non-formulary. Approved for restricted use by Consultant Dermatologists for anaesthesia before laser treatment where alternatives are not suitable (added to Dermatology specialist formulary list*).

\* Updates to specialist formulary lists may be delayed this month

## SMC Briefing Note:

[Click here](#) for July 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.

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