



### Special points of interest for Primary Care

- Domperidone - withdrawal from community pharmacies
- Nitrofurantoin in renal impairment

### SMC advice - September:

- Alogliptin (Vipidia®)
- Fingolimod (Gilenya®)
- Golimumab (Simponi®)
- Simeprevir (Olysio®)
- Tetracaine / lidocaine (Pliaglis 70 mg/g + 70 mg/g cream®)



## Prescribing Changes

### Aciclovir eye ointment - Herpes Simplex Keratitis

The prescribing status within the Tayside Area Formulary for aciclovir eye ointment has been changed from 'Hospital Only' to 'Can be prescribed by GPs under the direction of an Optometrist or Ophthalmologist'. Prescribing of aciclovir eye ointment can also therefore be by Independent Prescribing Optometrists. The College of Optometrists have clear Clinical Management Guidelines on when they can prescribe aciclovir eye ointment which includes recurrent herpes simplex keratitis where there is a clear history of previous attacks, no doubt about the diagnosis and only epithelial involvement. If stromal involvement, or epithelium not healed after 7 days, patients should be referred urgently to Ophthalmology. For acute herpes simplex this requires referral to Ophthalmology as starting treatment could make confirmation of the diagnosis more difficult.

Ganciclovir eye gel remains Hospital Only within the formulary, restricted to use in aciclovir-resistant herpetic keratitis.

### Inhaled ICS/LABA formulary choices

Formulary choices of ICS/LABA combination inhalers were updated at the end of August with the addition of a new indication for Fostair® (beclometasone and formoterol) to the formulary for symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. The NHS Tayside Respiratory MCN would like to clarify that Fostair® was added as first choice pMDI (pressurised metered dose inhaler) combination ICS/LABA for severe COPD and Seretide Accuhaler® is an equal first choice DPI (dry powder inhaler) combination ICS/LABA for severe COPD. Relvar Ellipta® is now the formulary second choice combination ICS/LABA inhaler for severe COPD.

When prescribers are initiating a combination ICS/LABA inhaler in patients with severe COPD the following points should be considered in order to prescribe the most appropriate formulary choice for the individual patient:

- Patient preference
- Inhaler technique
- Other inhaled devices they are prescribed

The inhaled device that the patient can and will use is the most important consideration, particularly when choosing between inhaled medicines that have an equal position within the formulary.

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## Drug Safety Updates

Please follow link - [Volume 8, Issue 2, September 2014](#)



## Drug Safety Updates - continued....

### Domperidone - withdrawal from Community Pharmacies

As a result of cardiac safety concerns with domperidone and previous restrictions on its use ( [Drug Safety Update, May 2014](#) ), a European review has recommended that Community pharmacists are no longer able to sell domperidone products. From September 4<sup>th</sup> 2014 domperidone is only available as a Prescription Only Medicine (POM).

A class 2 drug alert (action within 48hrs) was released on the 3<sup>rd</sup> of September recalling Motilium® 10 and Motilium® Instants from community pharmacies and wholesalers. These were Pharmacy Only Medicines (P) containing 10mg of domperidone, pack size, 1 x 10. Domperidone was available as a Pharmacy medicine for the short term use of nausea & vomiting (maximum duration 48 hours).

Patients requiring domperidone should now be referred to their GP.

Please note: domperidone products with legal status POM are not affected by the above recall.

[CLICK HERE](#) for Press Release. Information for patients can be accessed [HERE](#).

### Nitrofurantoin in renal impairment

A [recent review](#) by the MHRA has led to revised contraindications for the use of nitrofurantoin in renal impairment. Previously nitrofurantoin was contraindicated where creatinine clearance was less than 60ml/min. However, the MHRA have now concluded that this contraindication is no longer justified and has therefore revised this to state it is now contraindicated in patients with an eGFR of less than 45ml/min/1.73m<sup>2</sup>. Nitrofurantoin may also be used in short courses (3-7 days) with an eGFR of 30-44ml/min/1.73m<sup>2</sup>; but only for lower UTI with suspected or proven multidrug resistant pathogens, and only when benefits are thought to outweigh the risks.

NHS Tayside antibiotic guidance for lower UTI in renal impairment can be found [here](#).

Nitrofurantoin should usually only be considered for patients with renal impairment when the recommended agents are inappropriate.

Nitrofurantoin remains a first line choice treatment for lower UTI in females (3 days) and men (7 days) where there is no evidence of renal impairment.

Medicine	Indication	Local recommendation category	Comments and useful links
Alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia <sup>®</sup> ) (937/14) - Resubmission	For adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control 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> dual therapy <ul style="list-style-type: none"> <li>In combination with metformin, when metformin alone, together with diet and exercise does not provide adequate glycaemic control in patients for whom the addition of a sulfonylurea is inappropriate.</li> <li>In combination with a sulfonylurea, when sulfonylurea alone, together with diet and exercise does not provide adequate glycaemic control in patients for whom the addition of metformin is inappropriate due to contra-indications or intolerance.</li> </ul>	<b>Non-Formulary - absence of clinician demand</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Fingolimod, 0.5mg, hard capsules (Gilenya <sup>®</sup> ) (992/14) - Full submission	As a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups: - Patients with high disease activity despite treatment with at least one disease modifying therapy.  or - Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.  <b>SMC restriction:</b> For use in patients with rapidly evolving severe relapsing remitting multiple sclerosis. SMC has previously published advice concerning patients with high disease activity despite treatment with beta-interferon but not other disease modifying therapies.	<b>Non-Formulary - protocol pending</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Golimumab, 50mg and 100mg solution for injection (Simponi <sup>®</sup> ) (946/13) - Full submission	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.	<b>Not recommended</b>	<a href="#">SMC advice</a>
Simeprevir 150mg hard capsules (Olysio <sup>®</sup> ) (988/14) - Full submission	In combination with other medicinal products for the treatment of chronic hepatitis C in adult patients.	<b>Hospital Only - Hepatitis Team</b>  Gastroenterology Specialist List	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Tetracaine / lidocaine (Pliaglis 70 mg/g + 70 mg/g cream <sup>®</sup> ) (1000/14) - Non-submission	Local dermal anaesthesia on intact skin prior to dermatological procedures in adults.	<b>Not recommended</b>	<a href="#">SMC advice</a>  <i>Use only by Consultant Dermatologists for anaesthesia before laser treatment where alternatives not suitable</i>

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

# Tayside Area Formulary (TAF) Updates - Sep/Oct 2014

TAF Section	Drug(s)/topic	Changes
<a href="#">Chapter 3: Respiratory System</a> <a href="#">Respiratory Specialist Formulary List</a>	Asthma & COPD (Chronic Obstructive Pulmonary Disease)	<p>Links to BTS/SIGN Asthma guidance updated to latest version - <a href="#">SIGN 141 British guideline on the management of asthma, October 2014</a>.</p> <p>New sub-sections created for Asthma and Chronic Obstructive Pulmonary Disease within the following sections to make formulary choices clearer:</p> <ul style="list-style-type: none"> <li>03.01.01.01 Long-acting beta2 agonists</li> <li>03.01.02 Antimuscarinic bronchodilators</li> <li>03.02 Corticosteroids - Compound preparations</li> </ul> <p>Acetylcysteine SCA (Shared Care Agreement) removed from formulary and Respiratory specialist list as out of date. Updated version awaited.</p> <p>Azathioprine - link to GP letter removed from formulary and Respiratory specialist list as no longer accurate. Updated version awaited.</p>
<a href="#">04.05.01</a>	Orlistat	Link to <a href="#">Tayside Adult Weight Management Pathway</a> added (Staffnet intranet link).
<a href="#">05.03.03.02</a> <a href="#">Gastroenterology Specialist Formulary List</a>	Chronic hepatitis C	Simeprevir 150mg hard capsules (Olysio®) added to formulary and Gastroenterology Specialist Formulary List as Hospital Only - Hepatitis Team. See SMC advice on page 3.
<a href="#">06.01.02.04</a>	Dipeptidylpeptidase-4 inhibitors	Alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®) added as non-formulary. See SMC advice on page 3.
<a href="#">07.04.02</a>	Drugs for urinary frequency, enuresis, and incontinence	Link to <a href="#">Wound Management Continence Product Order Form</a> added to help users find this.
<a href="#">09.04</a>	Oral Nutrition	Links to <a href="#">Abbott adult oral nutritional supplement range</a> and <a href="#">Nutricia dysphagia product range</a> updated to the latest versions.
<a href="#">10.03</a>	Drugs for the treatment of soft-tissue disorders and topical pain relief	NHS Tayside Extravasation Policy removed as out of date. A new NOSCAN (North of Scotland Cancer Network) version is awaiting publication.
<a href="#">10.03.02</a>	Topical NSAIDs	Ibuprofen 5% topical gel added to formulary as a second choice topical NSAID. Piroxicam 0.5% topical gel remains the first choice topical NSAID.
<a href="#">11.03.03</a> <a href="#">Ophthalmology Specialist Formulary List</a>	Herpes Simplex Keratitis	Aciclovir 3% eye ointment changed from Hospital Only (Red traffic light) to Can be prescribed by GPs under the direction of an Optometrist or Ophthalmologist (Amber traffic light) for treatment of recurrent herpes simplex keratitis in formulary and on Ophthalmology Specialist Formulary List. See article on page 1 for further information.
<a href="#">Wound Management Formulary</a>	Section 1: Formulary dressings	<p>Updated to reflect current hospital ordering and new SKU code column added.</p> <p>Aquacel Foam: Non-adhesive dressings removed, Adhesive dressings added.</p> <p>Foam Adhesive Heels: Permafoam concave &amp; Mepilex heel added.</p> <p>Non-adherent Dressings: Tricotex changed to NA</p> <p>Aquacel Ag Extra changed to Aquacel Ag+ Extra</p> <p>Aquacel Ag changed to Aquacel Ag+</p>
	Section 5: Leg Ulcers Specialist List	Bullet point regarding a hydrofiber with polyurethane foam dressing removed from other considerations.

TAF Section	Drug(s)/topic	Changes
<a href="#">Wound Management Formulary</a>	Section 6: Pressure Ulcers	Bullet point regarding a hydrofiber with polyurethane foam dressing removed from other considerations. Fibrous hydrocolloid with foam added to treatment options.
	Section 7: Diabetic Foot Ulcers	Bullet point regarding a hydrofiber with polyurethane foam dressing removed from other considerations. Fibrous hydrocolloid with foam added to treatment options.
	Section 10: Wound Infection	Bullet point regarding a hydrofiber with polyurethane foam dressing removed from other considerations. Fibrous hydrocolloid with foam added to treatment options for Cavity Grade 1, 3 & 4. Section 10 split and renumbered to now reflect – Section 11: Fistulae/Sinuses/Cavities Section 12: Overgranulation Section 13: Fungating Wounds

## SMC Briefing Note:

[Click here](#) for August 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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