



Special Points of Interest for Primary Care

SMC Advice - February:

- albiglutide (Eperzan®)
- dulaglutide (Trulicity®)
- eculizumab (Soliris®)
- fulvestrant (Faslodex®)
- golimumab (Simponi®)
- guanfacine (Intuniv®)
- pixantrone (Pixuvri®)
- teduglutide (Revestive®)
- ulipristal acetate (Esmya®)

SMC Advice - March:

- capsaicin (Qutenza®)
- daptomycin (Cubicin®)
- enzalutamide (Xtandi®)
- eribulin (mesilate) (Halaven®)
- insulin detemir (Levemir®)
- nivolumab (Opvido®)
- oseltamavir (Tamiflu®)
- panobinostat (Farydak®)
- pertuzumab (Perjeta®)
- sacubitril/valsartan (Entresto®)

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Drug Safety Updates

Please follow link - Drug Safety Update Downloads - [February 2016](#) | [March 2016](#)

NHS Board New Medicines Decisions - National Standard Template -

Work has been undertaken nationally by the ADTC collaborative led by Health Improvement Scotland to develop standardised wording for use by Health Boards in recording local implementation of Scottish Medicines Consortium decisions

In Scotland, a newly licensed medicine is routinely available for use in an NHS board only after it has been:

- accepted for use in NHS Scotland by the Scottish Medicines Consortium (SMC), and/or
- accepted for use by the NHS board's Area Drug and Therapeutics Committee (ADTC).

There are six categories of decisions with standardised wording that will be used with immediate effect for all SMC decisions

- Available in line with national guidance (link to SMC advice)
- Available in line with local guidance for prescribing (link, if desired, to local guidance)
- Available from a specialist centre in another NHS board
- Not available as not recommended for use in NHS Scotland (link to relevant SMC advice)
- 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 (link to local guidance)
- 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 <enter date>

Boards were asked to implement the above wording and feedback any comments to Health Improvement Scotland in May 2016 to consider if the new wording captures adequately all local decisions.

Results of the Tayside Area Formulary User Survey

A link to a short survey (8 questions in total) for the Tayside Area Formulary (TAF) was included in Tayside DTC Supplement No. 153 Jan/Feb 2016. The survey was intended for healthcare professionals within NHS Tayside who use or may use the formulary. It aimed to explore the awareness of, and opinions on usability of, the formulary website and/or app. The survey ran for approximately 3 weeks (closed at 12 noon on Monday, 29th February).

Please [CLICK HERE](#) for DTC Supplement Extra with results from the TAF User Survey.



Guidelines and Protocols

Gonorrhoea and Antimicrobial Resistance

A [letter](#) from the Department of Health was sent to all GPs in England in December 2015 regarding the importance of antimicrobial stewardship when treating gonorrhoea, due to serious concerns about resistance and significant risks of untreatable disease. Although this letter has not been issued in Scotland the information is still relevant and it is therefore timely to highlight our local advice to prescribers.

NHS Tayside [guidance](#) is available for all primary care staff on testing for gonorrhoea. Local treatment guidelines are in line with the national guidance (injectable ceftriaxone and oral azithromycin). All positive tests should be referred to the Sexual Health service for review and treatment. If a patient will not agree to attend then the GP can obtain support and advice from the Consultant team via phone (07805762572) or email (Tay-UHB.TSRH@nhs.net).

For patients who present as a potential sexual contact, a full sexual health screen should be offered but antibiotic treatment should **not** be prescribed without testing. The oral antibiotic regime of cefixime and azithromycin is considered sub-optimal treatment and will increase the risk of resistance.

Prescribers are also reminded that testing is recommended in men presenting with UTI or epididymo-orchitis (follow [local guidance](#)) if they are under 35 or have had a new sexual partner in the last 3 months.

Antimicrobial Management Team and Sexual Health Service
January 2016

Prucalopride Protocol

The Area Drugs & Therapeutics Committee (ADTC) have approved the prescribing of prucalopride by GPs under the direction of the Pelvic floor Clinic in female patients responding to treatment after 12 months. A [local Prucalopride Treatment Protocol](#) has been written and the [Tayside Prucalopride Policy](#) has been updated to reflect this change.

Prucalopride, an SMC not recommended medicine, has been approved for local use, since February 2014, restricted to prescribing by or under the direction of consultant surgeons responsible for the Pelvic floor Clinic. Local audit results have demonstrated positive response to treatment in over 40% of patients, with some patients continuing to receive benefit for up to 2 years.

Indication: Treatment of chronic constipation in women who have not responded to standard laxative treatment after 6 months of therapy and have been referred to the Pelvic floor Clinic for assessment.

Monitoring of effectiveness: Patients are reviewed after 4 weeks of starting prucalopride and treatment stopped if not effective. Effective response is defined as 50% improvement of symptoms that can be quantified as at least one more spontaneous bowel movement per week. Patients responding to treatment will receive further prescriptions at 3 monthly intervals from the Pelvic floor Clinic, dispensed via hospital pharmacies.

Prolonged treatment: GPs may continue prescribing prucalopride under the direction of the Pelvic Floor Clinic in patients responding to treatment at 12 months.

The General Surgery specialist list and formulary have been updated to reflect this change.

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
<p>albiglutide 30mg and 50mg pre- filled pen (Eperzan[®])</p> <p>SMC 1024/15 Full submission Accepted Restricted</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 third line pre-insulin treatment option.</p>	<p>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</p>	<p>Link to formulary</p> <p>SMC Link</p>
<p>dulaglutide 0.75mg and 1.5mg solution for injection in pre-filled pen (Trulicity[®])</p> <p>SMC 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>Available in line with local guidance for prescribing</p>	<p>Formulary second line choice of weekly GLP-1 agonist</p> <p>Link to formulary</p> <p>SMC Link SPC Link</p>
<p>eculizumab 300mg concentrate for solution for infusion (Soliris[®])</p> <p>SMC 767/12 Non-submission Not recommended</p>	<p>In adults and children, for the treatment of patients with atypical haemolytic uremic syndrome (aHUS).</p>	<p>Not available as not recommended for use in NHS Scotland</p>	<p>SMC Link</p>
<p>fulvestrant, 250mg, solution for injection (Faslodex[®])</p> <p>SMC 114/04 Resubmission assessed under the end of life process Accepted</p>	<p>For the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.</p>	<p>Available in line with local guidance for prescribing</p>	<p>Hospital only Oncology</p> <p>SMC Link SPC Link</p>
<p>golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi[®])</p> <p>SMC 1124/16 Full submission Accepted</p>	<p>Treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).</p>	<p>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from clinical experts – decision expected by May 2016</p>	<p>SMC Link</p>
<p>guanfacine, 1mg, 2mg, 3mg and 4mg prolonged-release tablets (Intuniv[®])</p> <p>SMC 1123/16 Full submission Accepted</p>	<p>Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.</p>	<p>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from clinical experts – decision expected by May 2016</p>	<p>SMC Link</p>
<p>pixantrone 29 mg powder for concentrate for solution for infusion (Pixuvri[®])</p> <p>SMC 1138/16 Non-submission Not recommended</p>	<p>As monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non-Hodgkin B-cell Lymphomas.</p>	<p>Not available as not recommended for use in NHS Scotland</p>	<p>SMC Link</p>

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
teduglutide 5mg powder and solvent for solution for injection (Revestive®) SMC 1139/16 Non-submission Not recommended	For the treatment of adult patients with Short Bowel Syndrome.	Not available as not recommended for use in NHS Scotland	SMC Link
ulipristal acetate, 5mg, tablet (Esmya®) SMC 1128/16 Full submission Accepted	For the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	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

Medicine	Condition Being Treated	Board Decision	Comments and Useful Links
capsaicin 179mg cutaneous patch (Qutenza®) SMC 1140/16 Non-submission Not Recommended	Treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain.	Not available as not recommended for use in NHS Scotland	SMC Link
daptomycin powder for concentrate for solution for injection or infusion (Cubicin®) SMC 1141/16 Non-submission Not Recommended	Treatment of paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections.	Not available as not recommended for use in NHS Scotland	SMC Link
enzalutamide 40mg soft capsules (Xtandi®) SMC 1066/15 Independent Review Panel Accepted with PAS	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.	Available in line with national guidance	Hospital only Oncology SMC Link SPC Link
eribulin (mesilate) 0.44mg/mL solution for injection (Halaven®) SMC 1065/15 Resubmission Accepted Restricted with PAS	For the treatment of adult 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. <u>SMC restriction:</u> for use in patients with locally advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated.	Available in line with national guidance	Hospital only Oncology SMC Link SPC Link

Medicine	Condition Being Treated	Board Decision	Comments and Useful Links
<p>insulin detemir 100units/mL, solution for injection in cartridge (Penfill), pre-filled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®)</p> <p>SMC 1126/16 Abbreviated Submission Accepted Restricted</p>	<p>For treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.</p> <p><u>SMC restriction:</u> in patients unable to achieve good glycaemic control with established insulins.</p>	Available in line with national guidance	<p>SMC Link SPC Link</p>
<p>nivolumab 10mg/mL, concentrate for solution for infusion (Opdivo®)</p> <p>SMC 1120/16 Full Submission Not Recommended</p>	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults.	Not available as not recommended for use in NHS Scotland	SMC Link
<p>oseltamivir 30mg, 45mg, 75mg capsules and 6mg/ml powder for oral suspension (Tamiflu®)</p> <p>SMC 1127/16 Abbreviated Submission Accepted</p>	Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.	Available in line with National Guidance	<p>SMC Link SPC Links: 30 & 45mg capsules</p> <p>75mg capsules</p> <p>6mg/ml powder for oral suspension</p>
<p>panobinostat 10mg, 15mg and 20mg hard capsules (Farydak®)</p> <p>SMC 1122/16 Full submission considered under the end of life and orphan process Accepted</p>	In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent.	Available in line with local guidance for prescribing	<p>Hospital only Oncology</p> <p>SMC Link SPC Link</p>
<p>pertuzumab 420mg concentrate for solution for infusion vial (Perjeta®)</p> <p>SMC 1121/16 Full Submission Not Recommended</p>	For use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.	Not available as not recommended for use in NHS Scotland	SMC Link
<p>sacubitril/valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets (Entresto®)</p> <p>SMC 1132/16 Full Submission Accepted</p>	In adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.	Available in line with national guidance	<p>SMC Link SPC Link</p> <p>Flowchart for therapy in chronic heart failure</p>

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

No updates this month.



Tayside Area Formulary (TAF) Updates - March 2016

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
01.06.07	Other drugs used in constipation	Local prescribing information for prucalopride updated in line with updated Tayside Prucalopride Policy and new local Prucalopride Treatment Protocol . See page 2 for further information.
02.05.05.02	Angiotensin - II receptor antagonists	Addition of sacubitril/valsartan film-coated tablets (Entresto [®] ▼) to formulary and Cardiology specialist formulary list - GPs may prescribe under the direction of a heart failure specialist or Cardiologist (Amber traffic light). See SMC advice in table above. Flowchart for sequence of therapy for chronic heart failure developed and linked to formulary entry.
04.03.04	Other antidepressant drugs	Mirtazapine added to formulary and Renal specialist formulary list for uraemia induced pruritis in patients with advanced kidney disease [unlicensed use 'off-label'] under the direction of a renal specialist (Amber traffic light).
04.09.02	Antimuscarinic drugs used in parkinsonism	Tablet formulation of orphenadrine hydrochloride removed from formulary due to long term supply problem.
06.01.02.04	Dipeptidylpeptidase - 4 (DPP-4) inhibitors	Alogliptin now first choice DPP-4 inhibitor and sitagliptin now second choice DPP-4 inhibitor further to recommendation from Diabetes MCN.
06.01.02.05	Glucagon-like peptide-1 (GLP-1) receptor agonists and GLP-1 receptor agonists - once weekly	Addition of dulaglutide solution for injection in pre-filled pen (Trulicity [®] ▼) to formulary and Endocrinology specialist formulary list as second choice once weekly GLP-1 receptor agonist (Amber traffic light). Albiglutide pre filled pen (Eperzan [®] ▼) added as non-formulary. Exenatide (Bydureon [®]) once weekly M/R injection is the first choice once weekly GLP-1 receptor agonist. See SMC advice on page 3.
07.04.03	Other preparations for urinary disorders	Potassium citrate 3g granules for oral solution (Cystopurin [®]) added to formulary and Renal specialist formulary list for reduction of renal stone formation including patients with hypocitraturia and renal tubular acidosis [unlicensed use 'off-label'] if potassium citrate mixture is not tolerated (Amber traffic light).
13.9	Shampoos and other preparations for scalp and hair conditions	Updated prescribing advice following section review. Ketoconazole 2% shampoo now listed as first choice for seborrhoeic dermatitis. Selenium sulfide 2.5% shampoo added to formulary as second choice for seborrhoeic dermatitis where ketoconazole shampoo has not been tolerated. Dermax [®] shampoo (benzalkonium chloride 0.5%) added to formulary, useful as a mild descaling agent in seborrhoeic dermatitis or mild scalp psoriasis.
Specialist Formulary Lists	Oncology & Haematology Protocols/Clinical Management Guidelines	Link to protocols/guidelines updated to NOSCAN (North of Scotland Cancer Network) website for the most up to date information.

SMC Briefing Notes:

[February 2016](#) | [March 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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