



Special Points of Interest for Primary Care

SMC Advice

Published October:

- Aflibercept (Eylea®)
- Budesonide (Cortiment®)
- Budesonide/formoterol (Symbicort Turbohaler®)
- Budesonide/formoterol (Symbicort®)
- Golimumab (Simponi®)
- Lenvatinib (Lenvima®)
- Nivolumab (Opdivo®)
- Peramppanel (Fycompa®)
- Progesterone (Lutigest®)
- Rilpivirine/emtricitabine/tenofovir alafenamide (Odefsey®)
- Tocilizumab (RoActemra®)

Published November:

- Adalimumab (Humira®)
- Canakinumab (Ilaris®)
- Dequalinium (Fluomizin®)
- Fampridine (Fampyra®)
- Lenalidomide (Revlimid®)
- Migalastat (Galafold®)
- Nivolumab (Opdivo®)
- Olaparib (Lynparza®)
- Pegaspargase (Oncaspar®)
- Sofosbuvir (Epclusa®)



Drug Safety Updates

Please follow link - Drug Safety Updates 2016: [November 2016](#) | [December 2016](#)



Guidelines and Protocols

Methotrexate Injection

Tayside local prescribing committees have agreed that methotrexate injection may be prescribed in general practice under the direction of secondary care. Methotrexate injection for Rheumatology, Dermatology and Gastroenterology indications will move from a red traffic light (hospital only) to an amber traffic light (GP under the direction of a specialist) in the formulary once local guidance has been updated.

Prescribing Information Sources for Healthcare Professionals

A recent article in the Drug and Therapeutics Bulletin '[Prescribing information sources for healthcare professionals](#)' highlights resources that provide prescribing information about medicines and other sources of specialised information. An ATHENS password is required to access the full paper.

The resources provide high quality evidence based information about medicines and can be used to ensure drugs are prescribed safely and effectively. General resources covered include SPC, BNF, MIMS & CKS (Clinical Knowledge Summaries). More detailed information sources for clinical situations such as adverse effects, interactions and prescribing in renal/hepatic impairment as well as in pregnancy/lactation are also included.

Some of the resources highlighted are available via The Knowledge Network (www.knowledge.scot.nhs.uk) using ATHENS login. NHS employees can register for an Athens password via The Knowledge Network.

If further assistance is required with any medicine related enquiry, please do not hesitate to contact your locality or clinical pharmacist or contact Medicines Information on (01382) 632351 or email TAY-UHB.medinfo@nhs.net.

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Prescribing Changes

Co-danthramer Formulary Change

Co-danthramer and co-danthrusate are licensed for the treatment of constipation in terminally ill patients. Co-danthramer has been available as capsules (dantron 25mg, poloxamer '188' 200mg), strong capsules (dantron 37.5mg, poloxamer '188' 500mg), suspension (dantron 25mg, poloxamer '188' 200mg, per 5mL), and strong suspension (dantron 75mg, poloxamer '188' 1g, per 5mL). Co-danthrusate has been available as capsules (dantron 50mg, docusate sodium 60mg), and suspension (dantron 50mg, docusate sodium 60mg, per 5mL).

Discontinuation of co-danthramer capsules, strong co-danthramer capsules, and co-danthrusate capsules has arisen due to problems in sourcing one of the active ingredients, dantron. Dantron is an anthraquinone stimulant laxative, which acts on nerve endings in the colonic mucosa. Poloxamer '188' and docusate are wetting agents which act as stool softeners.

The formulary was updated last year to take account of the discontinuation of co-danthramer capsules. However, co-danthramer suspension had remained on the formulary at that time.

As suspensions of co-danthramer and co-danthrusate are significantly more costly than the discontinued capsules and other laxatives, an alternative to a co-danthramer or co-danthrusate product is use of a stimulant (senna) in combination with a stool softener (docusate sodium) (option A from the [Scottish Palliative Care Constipation guideline](#)) or use of a macrogol osmotic laxative (Laxido® Orange) (option B from the [Scottish Palliative Care Constipation guideline](#)). Both options may be equally effective and patient preferences should be taken into consideration.

The formulary has now been updated so all preparations of co-danthramer or co-danthrusate are non-formulary as per the Scottish Palliative Care Guidelines.



Information Technology

Link to Medusa (Injectable Medicines Guide)

The link to Medusa (Injectable Medicines Guide) has required to be removed from the home page of the Tayside Area Formulary.

A link to the Medusa website has been added to Clinical Systems on Staffnet (click on Clinical Systems in the left hand column on the homepage to access alphabetical list).

The link from the Pharmacy Staffnet site also remains active (found under 'Useful Links' in the right hand panel).

It would be helpful if this change could be highlighted to relevant colleagues, to ensure Medusa continues to be accessed as necessary (including out of hours).

Link to Oral Nutritional Supplements (ONS) Adult Formulary

It appears that some links have been removed and we are currently investigating why this has happened (it may be an IT issue).

The site can be accessed via <http://www.knowledge.scot.nhs.uk/taysidenutrition/oral-nutritional-support.aspx> and we ask if you could inform your colleagues of this in case they are also having difficulties.

The link from the home page of the formulary to the Tayside Nutrition Website (ONS support) has been corrected.

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Aflibercept 40mg/ml solution for injection (Eylea®) SMC 1186/16	For adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV).	Available in line with local guidance	SMC link SPC link
Budesonide 9mg prolonged release tablet (Cortiment®) SMC 1093/15	In adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient. SMC restriction: for use in patients with UC who present with active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone, as an alternative to budesonide rectal formulations or off-label oral budesonide	Available in line with national guidance	SMC link SPC link
Budesonide/formoterol 200mcg/6mcg inhalation powder and 400mcg/12mcg inhalation powder (Symbicort Turbohaler®) Budesonide/formoterol 200mcg/6mcg per actuation, pressurised inhalation, suspension (Symbicort®) SMC 1198/16	Treatment of patients with chronic obstructive pulmonary disease (COPD) with forced expiratory volume in 1 second (FEV1) 50% to 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.	Not available as not recommended for use in NHS Scotland.	SMC link
Golimumab 50mg solution for injection (Simponi®) SMC 1199/16	In combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with methotrexate.	Not available as not recommended for use in NHS Scotland.	SMC link
Lenvatinib 4mg and 10mg hard capsules (Lenvima®) SMC 1179/16	Treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).	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 January 2017	SMC link SPC link
Nivolumab, 10mg/ml, concentrate for solution for infusion (Opdivo®) SMC 1180/16	Treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. SMC Restriction: treatment with nivolumab is subject to a two year clinical stopping rule	Available in line with national guidance	SMC link SPC link
Perampanel 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film coated tablets (Fycompa®) SMC 1200/16	Adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy.	Not available as not recommended for use in NHS Scotland.	SMC link
Progesterone 100mg vaginal tablets (Lutigest®) SMC 1185/16	Luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women.	Available in line with national guidance	SMC link SPC link
Rilpivirine/emtricitabine/tenofovir alafenamide 200mg/25mg/25mg film-coated tablets (Odefsey®) SMC 1189/16	Treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg), infected with human immunodeficiency virus type 1 (HIV 1) without known mutations associated with resistance to the non nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV 1 RNA ≤100,000 copies/mL.	Available in line with national guidance	SMC link SPC link
Tocilizumab 162mg solution for injection in Pre-Filled Syringe (RoActemra®) SMC 1201/16	Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.	Not available as not recommended for use in NHS Scotland.	SMC link

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
Adalimumab 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen & Adalimumab 40mg/0.8ml vial for paediatric use (Humira®) SMC 1208/16	Treatment of moderately active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies	Not available as not recommended for use in NHS Scotland	SMC link
Adalimumab 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen & Adalimumab 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen (Humira®) SMC 1209/16	Treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate	Not available as not recommended for use in NHS Scotland	SMC link
Canakinumab 150mg powder for solution for injection (Ilaris®) SMC 1210/16	Treatment of active Still's disease including Adult-Onset Still's Disease who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate	Not available as not recommended for use in NHS Scotland	SMC link
Dequalinium chloride 10mg vaginal tablets (Fluomizin®) SMC 1194/16	Treatment of bacterial vaginosis. <u>SMC restriction:</u> In patients for whom the initial treatment is not effective or well tolerated	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 Formulary)	SMC link SPC link
Fampridine 10mg prolonged release tablets (Fampyra®) SMC 789/12	For the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS [expanded disability status scale] 4 to 7).	Not available as not recommended for use in NHS Scotland	SMC link
Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules (Revlimid®) SMC 1211/16	Treatment of adult patients with relapsed or refractory mantle cell lymphoma	Not available as not recommended for use in NHS Scotland	SMC link
Migalastat 123mg hard capsules (Galafold®) SMC 1196/16	Long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α -galactosidase A deficiency) and who have an amenable mutation. <u>SMC Restriction:</u> in males with classic mutations (leucocyte enzyme activity <1%) treatment should commence at diagnosis; in females and those males with later onset mutations with higher levels of leucocyte enzyme activity, treatment should commence when patients experience uncontrolled pain, evidence of renal, cardiac or neurovascular disease, or gastrointestinal symptoms that significantly reduce quality of life.	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 January 2017	SMC link SPC not available
Nivolumab 10mg/ml concentrate for solution for infusion (Opdivo®) SMC 1187/16	In combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults. <u>SMC restriction:</u> for the first-line treatment of advanced melanoma	Available in line with national guidance	SMC link SPC link
Nivolumab 10mg/ml concentrate for solution for infusion (Opdivo®) SMC 1188/16	As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults.	Not available as not recommended for use in NHS Scotland	SMC link
Olaparib 50mg hard capsules (Lynparza®) SMC No 1047/15	Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy	Available in line with national guidance	SMC link SPC link

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Pegaspargase 750U/mL solution for injection/infusion (Oncaspar®) SMC 1197/16	As a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients.	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 Formulary)	SMC link
Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) SMC 1195/16	Treatment of chronic hepatitis C virus (HCV) infection in adults. SMC Restriction: in patients with genotype 3 (GT3) chronic HCV infection.	Available in line with national guidance	SMC link SPC link

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 - December 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
01.05.02	Corticosteroids	Budesonide 9mg prolonged release tablet (Cortiment®) added to formulary and Gastroenterology specialist formulary list for prescribing by GPs under the direction of IBD/GI clinic (Amber traffic light) as per SMC restriction. See SMC advice on page 3.
01.06.02	Stimulant laxatives	Co-danthramer - all strengths and formulations (capsules, strong capsules, oral suspension, strong oral suspension) now non-formulary as all capsule formulations have been discontinued by the manufacturers. This is in line with Scottish Palliative Care Guidelines – Constipation guidance . For further information see article on page 2.
03.04.01	Sedating antihistamines	Alimemazine now non-formulary due to increased cost. Promethazine added as a second choice sedating antihistamine and hydroxyzine now listed as the third choice. Chlorphenamine remains the first choice sedating antihistamine.
05.03.01	HIV infection	Rilpivirine/emtricitabine/tenofovir alafenamide 200mg/25mg/25mg film-coated tablets (Odefsey®▼) added to formulary as per SMC advice (Hospital Only - HIV clinic). See SMC advice on page 3.
05.03.03.02	Chronic hepatitis C	Sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®▼) added to formulary and Gastroenterology specialist formulary list (Hospital Only) as per SMC advice. See SMC advice on page 5.
06.06.02	Denosumab	Denosumab (Xgeva®▼) added to formulary and Oncology & Haematology non-chemo drugs specialist formulary list for Oncology use only (Hospital Only) for the prevention of skeletal related events in adults with bone metastases from solid tumours when zoledronic acid is contraindicated.
08.03.04.02	Gonadorelin analogues	Leuprorelin acetate (Prostap® 3 DCS) prolonged-release injection now formulary choice of LHRH agonist for prostate cancer for prescribing by GPs under the direction of Urology/Oncology (Amber traffic light). Triptorelin (Decapeptyl® SR) modified release injection and goserelin (Zoladex® LA) implant now non-formulary. Urology and Oncology and Haematology non-chemo drugs specialist formulary lists updated.
10.01.01	Non-steroidal anti-inflammatory drugs	Diclofenac sodium e/c tablets – removed from formulary and Obstetrics & Gynaecology specialist formulary list for post partum analgesia. Only intramuscular injection and suppository formulations of diclofenac remain as formulary.
11.08.02	Subfoveal choroidal neovascularisation	Aflibercept 40mg/ml solution for injection (Eylea®▼) added to formulary and Ophthalmology specialist formulary list as an alternative to ranibizumab for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV) in adults. See SMC advice on page 3.
13.06.03	Topical preparations for rosacea	Brimonidine tartrate 0.33% gel – link to MHRA Drug Safety Update – Brimonidine gel (Mirvaso): risk of exacerbation of rosacea, Nov 2016 added. Advice for healthcare professionals from article added as prescribing notes in formulary entry.

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 either:

David Gill
Lead Clinician - Pharmacoeconomics
email: david.gill@nhs.net

or

Claire James
Senior Pharmacist - Clinical Effectiveness
email: clairejames@nhs.net