



### Special points of interest for Primary Care

- Duloxetine for neuropathic pain
- Tramadol & other CD changes

#### SMC advice:

- Adapalene (Epiduo®)
- Aflibercept, (Eylea®)
- Azithromycin (Zedbac®)
- Dimethyl fumarate (Tecfidera®)
- Emtricitabine, rilpivirine, tenofovir disoproxil (as fumarate) (Eviplera®)
- Lenalidomide (Revlimid®)
- Lipegfilgrastim (Lonquex®)
- Macitentan (Opsumit®)

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## Guidelines and Protocols

### Duloxetine for neuropathic pain

A local treatment protocol for duloxetine capsules (Cymbalta®) for use in other peripheral neuropathic pain syndromes [off-label] (licensed for diabetic peripheral neuropathic pain) has been published ([CLICK HERE](#)).

The use of duloxetine (Cymbalta®) in other neuropathic pain syndromes [off-label] has been investigated with small randomised controlled trials showing a decrease in pain responses. Both SIGN and NICE acknowledge the role of off-label use of duloxetine in controlling neuropathic pain symptoms.

#### Local recommendation

Restricted to use in patients who are intolerant of first, second, or third-line options (involving amitriptyline, gabapentin and pregabalin) for the treatment of neuropathic pain or where these treatments have been ineffective.

GPs may prescribe under the direction of the Pain Clinic, following initiation and 2 week review by the Pain Clinic.



## Prescribing Changes

### Tramadol, lisdexamfetamine, zopiclone & zaleplon - Controlled Drug (CD) changes

The Home Office has announced changes to the legal classification of certain medicines and the following legislative changes will come into force on Tuesday 10th June 2014.

**Tramadol** will become a schedule 3 CD. It will be exempt from the Safe Custody Regulations ( i.e. does not need to be stored in a CD cupboard) but will be subject to the **full CD prescription writing and requisition requirements**. This change has been prompted by increasing reports of misuse and harm. Of the 581 drug related deaths in Scotland in 2012, tramadol was present or implicated as a contributory factor in 48 cases.

**Lisdexamfetamine** will become a schedule 2 CD like dexamfetamine (requiring safe storage, record keeping and prescription requirements).

**Zopiclone & zaleplon** will become schedule 4 (part I) CDs, like zolpidem and most benzodiazepines.

From the 10th of June prescribers will need to ensure that all prescriptions meet the updated legal requirements. Primary care practitioners should note that none of the above medicines can be included in the serial prescription system from this date.

[Click here](#) to access Frequently Asked Questions about the tramadol changes.



## Drug Safety Updates

Please follow link - [Volume 7, Issue 10, May 2014](#)

Medicine	Indication	Local recommendation category	Comments and useful links
Adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) (682/11) - Resubmission	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. <b>SMC restriction:</b> the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate.	<b>Non-Formulary - Absence of clinician demand</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a> <i>Individual constituents core formulary. Adapalene 0.1%. Benzoyl peroxide 4%, 5% &amp; 10%</i>
Aflibercept, 40mg/mL solution for injection (Eylea®) (954/14) - Full submission	For adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.	<b>Hospital Only</b> <b>2nd line choice - in patients commenced treatment elsewhere</b> Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>1st line - Ranibizumab</i>
Azithromycin 500mg powder for solution for infusion (Zedbac®) (950/14) - Abbreviated submission	The treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required.	<b>Hospital Only</b>  Under direction of ID or Microbiology.  <b>2nd line to IV clarithromycin</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®) (886/13) - Full submission	Treatment of adult patients with relapsing remitting multiple sclerosis.	<b>Hospital Only - Neurology</b>  1st line for new patients.   Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link (120mg)</a> <a href="#">SPC link (240mg)</a>  <i>Alternative for patients currently prescribed beta interferon or glatiramer for RRMS.</i>
Emtricitabine 200mg, rilpivirine 25mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®) (951/14) - Full submission	Treatment of adults 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 ≤100,000 HIV-1 RNA copies/mL. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®.	<b>Hospital Only - HIV Clinic</b>  <b>2nd line choice</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Lenalidomide, 5mg, 10mg, 15mg and 25mg hard capsules (Revlimid®) (441/08) - Resubmission	In combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy). <b>SMC restriction:</b> to use at first relapse in patients who have received prior therapy with bortezomib in whom thalidomide has not been tolerated or is contraindicated.	<b>Formulary</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  NOSCAN protocol in development
Lipegfilgrastim, 6mg, solution for injection (Lonquex®) (908/13) - Full submission	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). <b>SMC restriction:</b> where a long-acting granulocyte-colony-stimulating factor is appropriate.	<b>Non-Formulary - alternatives preferred</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Pegfilgrastim &amp; lenograstim formulary choices</i>

\* 'pending' means that no local recommendation to support use is in place at the current time

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

Medicine	Indication	Local recommendation category	Comments and useful links
Macitentan, 10mg film-coated tablets (Opsumit®) (952/14) - Full submission	As monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension in adult patients of World Health Organisation Functional Class II to III.  <b>SMC restriction:</b> to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or similar specialists.	<b>Restricted to initiation &amp; supply by specialists working in the Scottish Pulmonary Vascular Unit, Glasgow</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>

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## Tayside Area Formulary (TAF) Updates - Apr/May 2014

TAF Section	Drug(s)/topic	Changes
<a href="#">4.7.3 &amp; netFormulary*</a> <a href="#">Chronic Pain specialist list</a>	Neuropathic pain	Duloxetine for the treatment of peripheral neuropathic pain (non-diabetic) [off-label] added to Chronic Pain specialist formulary list and formulary (GPs may prescribe under the direction of the Pain Clinic). Restricted to use in patients who are intolerant of first, second, or third-line options for the treatment of neuropathic pain or where these treatments have been ineffective. GPs may prescribe under the direction of the Pain Clinic, following initiation and 2 week review by the Pain Clinic. See <a href="#">local treatment protocol</a>
<a href="#">11.8.2 &amp; netFormulary*</a> <a href="#">Ophthalmology specialist list</a>	Subfoveal choroidal neovascularisation	Aflibercept (Eylea®) added to Ophthalmology specialist formulary list and formulary (Hospital-Only) as 2nd line choice for treatment of visual impairment due to macular oedema (MO) secondary to central retinal vein occlusion (CRVO) (see page 2 for SMC advice).

\* Tayside netFormulary currently under development and not available for open access

**SMC Briefing Note:**  
[Click here](#) for April 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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