



Special points of interest for Primary Care

- Levonorgestrel (Upostelle®)

SMC advice:

- Colestilan (BindRen®)
- Fluocinolone acetonide (Iluvien®)
- Levonorgestrel (Upostelle®)
- Lomitapide (Lojuxta®)
- Timolol (TiopeX®)



Specialist lists - progress

The Epilepsy specialist formulary list was postponed at the February Medicines Advisory Group (MAG) meeting until the new SIGN guideline for Epilepsy is published. The draft guideline has recently undergone consultation and is due to be published later in the year.



Guidelines and Protocols

Pirfenidone Protocol

The new medicine treatment protocol for pirfenidone (Esbriet®▼) has been published ([click here](#)). Pirfenidone is indicated for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.

Local recommendation

HOSPITAL ONLY. Pirfenidone is prescribed only by hospital specialists in interstitial lung disease.

The local recommendation following SMC advice for pirfenidone was published in the [Tayside DTC supplement no. 130](#) (Sept/Oct 2013).

Pirfenidone will be added to the near patient testing LES as it requires LFT monitoring prior to initiation (undertaken by secondary care), then at month 1, 2, 3, 4, 5, 6, then every 3 months thereafter (undertaken by primary care). Blood monitoring results will also be reviewed at routine clinic visits.

Further information on pirfenidone and monitoring is within the [local new medicine treatment protocol](#) and [letter](#) from the Interstitial Lung Disease Clinic which would be sent to the GP when a patient is initiated on treatment.

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Drug Safety Updates

Please follow link - [Volume 7, Issue 8, March 2014](#)



Supply problems - valsartan

Several suppliers are experiencing intermittent supply issues with valsartan capsules and tablets which may last several months. Clinicians may, in some cases, need to consider switching patients to an alternative angiotensin-II receptor antagonist (AIIA).

Valsartan is one of several AIIAs on the UK market which are all licensed for the treatment of hypertension but differ in their other licensed indications.

Valsartan is recommended within the Tayside Area Formulary only for treatment of post-MI patients with clinical evidence of heart failure and/or left ventricular systolic dysfunction who are unable to tolerate ACE-inhibitors.

Valsartan is also licensed for the treatment of hypertension and symptomatic heart failure.

Alternative AIIAs within the [Tayside Area Formulary](#) include:

- Losartan - Hypertension if patients have not tolerated an ACE-inhibitor
- Candesartan - Heart failure for patients intolerant of ACE-inhibitors

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Supply problems - valsartan (continued).....

Information on dose equivalence of AIIRAs is not available, so when changing a patient from one AIIRA to another, the dosing range within which the dose falls should be taken into account (i.e. bottom, middle, or top of the dosing range). It should be noted that valsartan is the only AIIRA licensed for use in the post-MI setting and specialist advice should be sought if an alternative AIIRA is required. In addition, patients on a twice daily dosing regimen of valsartan will need to be advised of a change to a once daily regimen on switching to an alternative AIIRA, to reduce the risk of a dosing error.

The following approximate dose conversions for AIIRAs has been produced by UK Medicines Information (UKMI):

AIIRA	Approximate dose conversions*			
Valsartan	40mg DAILY**	80mg DAILY**	160mg DAILY**	320mg DAILY**
Candesartan	4mg OD	8mg OD	16mg OD	16mg OD to 32mg OD
Losartan	25mg OD	50mg OD	100mg OD

**Dose equivalencies are approximate and individual responses may vary so blood pressure should be monitored following the switch and dosing adjusted accordingly, if needed.*

***Dose may be given as two divided doses depending on indication*

In addition to blood pressure monitoring following a switch, renal function and serum potassium should be monitored as appropriate to the individual patient (i.e. according to patient's usual monitoring requirements and stability of renal function).

[Click Here](#) to access section 2.5 (including angiotensin-II receptor antagonists) of the Tayside Area Formulary.



Prescribing Changes

Prucalopride

Prucalopride (Resolor®) is licensed for the symptomatic treatment of chronic constipation in woman in whom laxatives fail to provide adequate pain relief. This medicine was SMC not recommended in July 2011 following a resubmission and has been prescribed in NHS Tayside via the Individual Patient Treatment Request. [Click here for SMC advice.](#)

Recently the Tayside Area Drug & Therapeutics Committee has approved the limited use of prucalopride in a small number of female patients who have failed all other treatment options for chronic constipation & the next therapeutic option is invasive therapy. Use of the drug will be monitored & data will be presented to the ADTC in a year's time (March 2015).

Prescribing is restricted to **Hospital Only** under the 3 named consultant surgeons responsible for the Pelvic Floor Clinic.

The drug will remain non formulary. [Click here](#) for a link to the local policy.

Medicine	Indication	Local recommendation category	Comments and useful links
Colestilan 1g film-coated tablet, 2g and 3g granules sachet (BindRen®) (939/14) - Full submission	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	Not recommended	SMC advice
Fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) (864/13) - Resubmission	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. SMC restriction: <ul style="list-style-type: none"> only in patients in whom the affected eye is pseudophakic (has an artificial lens after cataract surgery) and; retreatment would take place only if the patient had previously responded to treatment with fluocinolone acetonide and subsequently best corrected visual acuity had deteriorated to less than 20/32. 	Non Formulary - absence of clinician demand Supplied via a Patient Access Scheme	SMC advice SPC link
Levonorgestrel 1500microgram tablet (Upostelle®) (938/14) - Abbreviated submission	Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.	Formulary - 1st line choice	SMC advice SPC link <i>Upostelle® brand replaces Levonelle® in formulary</i>
Lomitapide (Lojuxta®) 5mg, 10 mg, 20mg hard capsules (956/14) - Non-submission	Adjunct to a low-fat diet and other lipid-lowering medicinal products with or without low density lipoprotein (LDL) apheresis in adult patients with homozygous familial hypercholesterolaemia (HoFH).	Not recommended	SMC advice
Timolol, 1mg/g eye gel for single-dose container (Tiopex®) (941/14) - Abbreviated submission	Reduction of the elevated intraocular pressure in patients with: <ul style="list-style-type: none"> - ocular hypertension, - chronic open angle glaucoma. SMC restriction: to use in patients who have proven sensitivity to preservatives.	Non-formulary - alternatives preferred	SMC advice SPC link <i>Preservative free 0.25 & 0.5% on formulary for restricted use</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 \(including Individual Patient Treatment Requests\)](#)'

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

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Colistimethate sodium dry powder for Inhalation, hard capsules, 1.66 million units/capsule (Colobreathe®) NICE TA 276; March 2013	Treatment for chronic pseudomonas lung infection in cystic fibrosis patients who would benefit from continued colistimethate sodium treatment but cannot take it in its nebulised form & would otherwise be offered tobramycin treatment (more expensive).	GPs under the direction of secondary care Respiratory Specialist List Supplied via a Patient Access Scheme	NICE TA 276 Shared Care Agreement - Colistimethate nebulised & inhaled Click here for SCA

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Respiratory	Colistimethate sodium dry powder for Inhalation (hard capsules) (Colobreathe [®]) added to Respiratory specialist list (GPs may prescribe under specialist direction). Shared Care Agreement updated (nebulised and inhaled). Link to pirfenidone local treatment protocol and GP letter added to Respiratory specialist list.
3.1 & netFormulary*	Long-acting antimuscarinic bronchodilators / COPD	Formulary 1st choice antimuscarinic bronchodilator now glycopyrronium (Seebri Breezhaler [®]), 2nd choice now aclidinium (Eklira Genuair [®]), 3rd choice now tiotropium (Spiriva HandiHaler [®]).
3.2 & netFormulary*	Inhaled corticosteroids-compound preparation	Seretide Evohaler [®] removed from formulary. Seretide 500 Accuhaler [®] remains as first choice in COPD where combined inhaled steroid and long-acting bronchodilator indicated. Seretide 100 Accuhaler [®] and Seretide 250 Accuhaler [®] removed from formulary.
3.1.1 & netFormulary*	Pirfenidone	Link to pifenidone local treatment protocol and GP letter added.
7.3	Emergency hormonal contraception	Levonorgestrel 1500microgram tablet (Upostelle [®]) added to formulary as 1st choice for emergency hormonal contraception. See SMC advice on page 3. Upostelle [®] brand replaces Levonelle [®] .

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

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