



### Special points of interest for Primary Care

- Cinacalcet local protocol
- Palliative care guidelines
- Dexamethasone—Injection

### SMC advice - October:

- Alogliptin & metformin (Vipdomet®)
- Azelastine hydrochloride plus fluticasone propionate nasal spray (Dymista® nasal spray)
- Brentuximab vedotin (Adcetris®)
- Capsaicin, 179mg, cutaneous patch (Qutenza®)
- Dabigatran etexilate (Pradaxa®)
- Empagliflozin 10mg and 25mg tablet (Jardiance®)
- Lurasidone (Latuda®)
- Misoprostol (Mysodelle®)
- Posaconazole 100mg gastro-resistant tablets (Noxafil®)
- Trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla®)

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## Guidelines and Protocols

### Cinacalcet (Mimpara®) local treatment protocol

A local treatment protocol has been developed for cinacalcet tablets. Cinacalcet is a calcimimetic agent which directly lowers PTH levels by increasing the sensitivity of the calcium sensing receptor to extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.

Cinacalcet is prescribed in line with the NICE MTA 117, published in January 2007. This states that cinacalcet should be reserved for treatment of refractory secondary hyperparathyroidism in patients with end-stage renal disease only in those:

- Who have 'very uncontrolled' plasma levels of intact parathyroid hormone (PTH) (>85pmol/litre) that are refractory to standard therapy, and a normal or high adjusted serum calcium level

AND

- In whom surgical parathyroidectomy is contraindicated, in that the risks of surgery are considered to outweigh the benefits

### Local recommendation

GPs may prescribe under the direction of a Renal Physician (in line with NICE MTA 117).

**Prescriber details:** Initiated by Renal Consultant or Associate Specialist in Renal Medicine. Prescribed by GP under the direction of the Renal Physicians. Reviewed and titrated by Renal Consultants at Renal Clinic or when attending the haemodialysis unit.

### Monitoring - response to treatment:

Monitoring will be carried out when the patient attends the Renal Dialysis Unit or Renal Clinic. Patients maintained on peritoneal dialysis may be asked to attend their GP Surgery for blood samples to be taken for checking of serum calcium. It will be the responsibility of the Renal Consultant to check the result, and modify treatment if necessary.

[CLICK HERE](#) for the local treatment protocol.

## NHS Scotland Palliative Care Guidelines

The website for the NHS Scotland Palliative Care Guidelines has been updated following a review and was launched on 18th November 2014 as The Scottish Palliative Care Guidelines. The website URL remains the same: <http://www.palliativecareguidelines.scot.nhs.uk/> although links to individual sections and drug monographs have been updated. Links within the Tayside Area Formulary to the Scottish Palliative Care Guidelines have been updated.

Medicines within the updated guidelines are now classified as Red, Amber or Green as follows:

**Red** – For medicines normally initiated and used under specialist guidance

**Amber** – For medicines normally initiated by a specialist but may be used by generalists

**Green** – For medicines routinely initiated and used by generalists

The following symbols are also now included next to medicines where appropriate:

† - Indicates this use is off licence [or off-label]

QT - Indicates this medication is associated with QT prolongation



## Drug Safety Updates

Please follow link - [Volume 8, Issue 3, October 2014](#)  
[Volume 8, Issue 4, November 2014](#)



## Drug Safety Updates - continued....

### Dexamethasone injection differing strengths

Dexamethasone 4mg/mL injection (manufactured by Organon) has been discontinued.

There are three different preparations and two strengths of dexamethasone injection available – 3.3mg/mL (Hameln & Hospira brand) and 3.8mg/mL (Aspen brand).

Prescribing of dexamethasone should continue to be expressed in terms of dexamethasone base. A dosing chart—[click here](#) has been produced to give guidance on volume of dexamethasone 3.3mg/mL to use to give doses of 4mg dexamethasone base or multiples thereof.

**To avoid confusion NHS Tayside hospitals only stock dexamethasone 3.3mg/mL injection—Hameln brand.**

#### Important differences:

- Vials of the Hospira brand of dexamethasone 3.3mg/mL contain sodium sulphite AND MUST NOT BE USED FOR INTRATHECAL USE.
- Dexamethasone injection 3.8mg/mL (Aspen brand) requires refrigeration.

**If prescribing is to continue on discharge please communicate the brand & strength of dexamethasone injection.**

For further information contact your local pharmacist or Medicines Information services on 01382 632351.



## Prescribing Changes

### Discontinuation of Tegretol® Chewtabs (carbamazepine)

Novartis have [written to healthcare professionals](#) advising of the discontinuation of supply of Tegretol® (carbamazepine) Chewtabs (100mg and 200mg). Based on current demand the supply of the 100mg Chewtab is expected to be depleted by May 2015 and the 200mg Chewtab by end of October 2014.

Carbamazepine liquid is the recommended alternative, however switching to alternative treatment is a clinical decision based upon the individual patient. The bioavailability from various oral formulations of carbamazepine has been reported to lie between 85-100%. Therefore changing the formulation (if required) of carbamazepine prescribed for epilepsy should be done only after Neurology specialist review or on advice from Neurology, with caution and close monitoring, and following discussion between patient and clinician.

The formulary will be amended to remove the Chewtabs formulation from the carbamazepine entry.

### Discontinuation of pipotiazine palmitate (Piportil® Depot)

A [direct healthcare professional communication](#) has been sent out by Sanofi Aventis to advise of the discontinuation of supply of Piportil® Depot (pipotiazine palmitate) injection. Based on current estimates it is anticipated that this will no longer be available from the end of March 2015.

The manufacturer has advised the following:

- No new patients should be initiated on pipotiazine palmitate
- Patients currently prescribed pipotiazine palmitate should be switched to alternative treatment with appropriate medical supervision, following review and discussion between patient and clinician.

Within NHS Tayside, Mental Health cannot advise on a specific alternative and each case will need to be reviewed on an individual basis. Mental Health clinicians have been made aware of this so steps are taken to review each patient. The majority of prescribing and administration of pipotiazine palmitate will be via Mental Health services. However there may be one or two patients on GP caseloads that will need reviewed.

The formulary will be amended to list pipotiazine palmitate depot injection as non-formulary and discontinued. It will be removed from the Mental Health specialist formulary list.

Medicine	Indication	Local recommendation category	Comments and useful links
Alogliptin 12.5mg plus metformin 1000mg combination tablet (Vipdomet®) (998/14) - Abbreviated submission	In the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus: <ul style="list-style-type: none"> <li>as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin.</li> <li>in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone.</li> <li>in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.</li> </ul> <b>SMC restriction:</b> to use in patients for whom this fixed dose combination of alogliptin and metformin is an appropriate choice of therapy and only when the addition of a sulphonylurea to metformin monotherapy is not appropriate.	<b>Non-Formulary - absence of clinician demand</b>	<a href="#">SMC advice</a>
Azelastine hydrochloride 137micrograms plus fluticasone propionate 50micrograms per actuation nasal spray (Dymista® nasal spray) (921/13) - Abbreviated submission	For the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	<b>Non-Formulary - protocol pending</b>  Supplied via a Patient Access Scheme	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Brentuximab vedotin (Adcetris®) 50mg powder for concentrate for solution for infusion (989/14) - Full submission	Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): <ol style="list-style-type: none"> <li>following autologous stem cell transplant (ASCT) or</li> <li>following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option and</li> </ol> treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).  <b>SMC restriction:</b> treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): <ol style="list-style-type: none"> <li>following autologous stem cell transplant (ASCT) or</li> <li>following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.</li> </ol>	<b>Hospital Only</b> <b>Haematology</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Capsaicin, 179mg, cutaneous patch (Qutenza®) (673/11) - Resubmission	For the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.  <b>SMC restriction:</b> to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments.	<b>Formulary - Hospital Only</b> <b>4th line</b>  <b>Chronic Pain Specialist List</b>	<a href="#">SMC advice</a> <a href="#">SPC link</a>  <i>Non-formulary for postherpetic neuralgia</i>

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

Medicine	Indication	Local recommendation category	Comments and useful links
Dabigatran etexilate, 110mg, 150mg capsules (Pradaxa <sup>®</sup> ) (995/14) - Full submission	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	Non-Formulary - absence of clinician demand	<a href="#">SMC advice</a>
Empagliflozin 10mg and 25mg tablet (Jardiance <sup>®</sup> ) (993/14) - Full submission	Treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy: 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> to use in the following situations: <ul style="list-style-type: none"> <li>• dual therapy in combination with metformin, when a sulphonylurea is inappropriate.</li> <li>• triple therapy in combination with metformin plus standard of care.</li> <li>• add-on to insulin therapy in combination with insulin plus standard of care.</li> </ul>	Non-Formulary - absence of clinician demand	<a href="#">SMC advice</a>
Lurasidone, 18.5mg, 37mg, 74mg film-coated tablets (Latuda <sup>®</sup> ) (994/14) - Full submission	For the treatment of schizophrenia in adults aged 18 years and over. <b>SMC Restriction:</b> as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects.	Formulary GPs may prescribe under the direction of Mental Health Mental Health Specialist List	<a href="#">SMC advice</a> <a href="#">SPC link</a> Alternative to aripiprazole
Misoprostol, 200 microgram, vaginal delivery system (Mysodelle <sup>®</sup> ) (996/14) - Full submission	Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.	Non-Formulary - absence of clinician demand	<a href="#">SMC advice</a>
Posaconazole 100mg gastro-resistant tablets (Noxafil <sup>®</sup> ) (999/14) - Abbreviated submission	In the treatment of the following fungal infections in adults: <ul style="list-style-type: none"> <li>• Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;</li> <li>• Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B;</li> <li>• Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole;</li> <li>• Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.</li> </ul> For prophylaxis of invasive fungal infections in the following patients: <ul style="list-style-type: none"> <li>• Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections;</li> </ul> (continued on page 5)	Formulary - Hospital Only Haematology	<a href="#">SMC advice</a> <a href="#">SPC link</a> <i>Posaconazole suspension also available but is not interchangeable with the tablets due to differences in dosing of each formulation</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 \(including Individual Patient Treatment Requests\)](#)'

Medicine	Indication	Local recommendation category	Comments and useful links
Posaconazole 100mg gastro-resistant tablets (Noxafil®) (999/14) - Abbreviated submission (continued)	<ul style="list-style-type: none"> <li>Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections.</li> </ul> <p><b>SMC restriction:</b> to patients in whom there is a specific risk of <i>Aspergillus</i> infection or where fluconazole or itraconazole are not tolerated on the advice of local microbiologists or specialists in infectious diseases.</p>	Formulary - Hospital Only Haematology	<a href="#">SMC advice</a> <a href="#">SPC link</a> <i>Posaconazole suspension also available but is not interchangeable with the tablets due to differences in dosing of each formulation</i>
Trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla®) (990/14) - Full submission	<p>As a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:</p> <ul style="list-style-type: none"> <li>Received prior therapy for locally advanced or metastatic disease, or</li> <li>Developed disease recurrence during or within six months of completing adjuvant therapy.</li> </ul>	Not recommended	<a href="#">SMC advice</a>

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

### Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Cinacalcet 30mg, 60mg, 90mg tablets (Mimpara®) - NICE MTA 117, January 2007  Update to NHS Tayside DTC recommendation from DTC supplement no. 66, February 2007.	Severe refractory secondary hyperparathyroidism (as defined within <a href="#">NICE MTA 117</a> ) and in whom parathyroidectomy is contraindicated (e.g. those in whom surgery and/or general anaesthetic would be high risk or patients unfit for surgery)	Formulary GPs may prescribe under the direction of a Renal physician Renal Specialist List	<a href="#">Local treatment protocol</a>



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

TAF Section	Drug(s)/topic	Changes
<a href="#">01.01</a>	Dyspepsia and gastro-oesophageal reflux disease	Link to NICE CG17 - Dyspepsia updated to <a href="#">NICE CG184: Dyspepsia and gastro-oesophageal reflux disease: Investigation and management of dyspepsia, symptoms suggestive of gastro-</a>
<a href="#">01.01.02</a>	Compound alginate preparations	Gastrocote® tablets and sugar-free liquid removed from formulary as discontinued by manufacturer. Peptac® liquid and Gaviscon® Advance tablets or liquid remain as formulary alternatives.
<a href="#">02.01, 02.03, 02.04, 02.06.02, 02.09</a>	Atrial fibrillation	Links to NICE CG36 - Atrial fibrillation updated to <a href="#">NICE CG180: Atrial fibrillation: the management of atrial fibrillation, June 2014</a> .
<a href="#">04.02.01</a>	Second-Generation Antipsychotic Drugs	Lurasidone, 18.5mg, 37mg, 74mg film-coated tablets (Latuda®) added to formulary and Mental Health Specialist Formulary List* for schizophrenia as Amber traffic light (GPs may prescribe under the direction of Mental Health). See SMC advice on page 4. Alternative to aripiprazole in patients in whom it is important to avoid weight gain and metabolic adverse effects. See formulary entry for further information including drug interactions.

\* Updates to Specialist Formulary Lists may be delayed this month

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# TAF Updates - Oct/Nov 2014 continued.....

TAF Section	Drug(s)/topic	Changes
<a href="#">04.02.02</a>	Antipsychotic depot injections	Pipotiazine palmitate (Pipartil® Depot) injection changed to non-formulary as discontinued by manufacturer. Information on discontinuation added to non-formulary entry. Removed from Mental Health Specialist Formulary List.* For further information see page 2.
<a href="#">04.02.03</a>	Drugs used for mania and hypomania	Link to NICE CG38 - Bipolar disorder updated to <a href="#">NICE CG185: Bipolar disorder, Sept 2014</a> . Link also updated on Mental Health Specialist Formulary List.*  Chewtabs formulation of carbamazepine removed as discontinued. See page 2.
<a href="#">04.07.02</a>	Opioid analgesics - Severe pain (step 3)	Statement added at top of formulary section to emphasise differences between modified release (MR) opioid preparations for background pain and immediate release (IR) opioid preparations for breakthrough pain. Links to <a href="#">NPSA guidance - Reducing Dosing Errors with Opioid Medicines, July 2008</a> and the <a href="#">NHS Tayside Safe and Secure Handling of Medicines</a> added.  Difference between MR tablets and IR capsules emphasised for oxycodone entry. Links to <a href="#">Oxycodone MR Stepdown advice</a> and <a href="#">Local Treatment Protocol for Oxycodone MR in the Acute Pain Setting</a> updated to most recent versions.
<a href="#">04.07.03</a>	Neuropathic pain	Capsaicin, 179mg, cutaneous patch (Qutenza®) added to formulary and Chronic Pain Specialist Formulary List* as Hospital Only (Red traffic light). See SMC advice on page 3.
<a href="#">04.08.01</a>	Control of epilepsy	Chewtabs formulation of carbamazepine removed as discontinued. For further information see page 2.
<a href="#">05.02.01</a>	Triazole antifungals	Indication for oral voriconazole in aspergillus related lung disease where itraconazole is ineffective or otherwise inappropriate added to formulary and Respiratory Specialist Formulary List* as Amber traffic light (as per <a href="#">Shared Care Agreement</a> ).  Posaconazole 100mg gastro-resistant tablets (Noxafil®) added to formulary as Hospital Only-Haematology. See SMC advice on page 4 and 5.
<a href="#">06.01.02.04</a>	Dipeptidylpeptidase-4 inhibitors	Alogliptin 12.5mg plus metformin 1000mg combination tablet (Vipdomet®) added as non-formulary. See SMC advice on page 3.
<a href="#">06.01.02.06</a>	Other antidiabetic drugs	Empagliflozin 10mg and 25mg tablet (Jardiance®) added as non-formulary. See SMC advice on page 4.
<a href="#">09.05.01.02</a>	Hypercalcaemia and hypercalciuria	Cinacalcet 30mg, 60mg, 90mg tablets (Mimpara®) changed to Amber prescribing status (GPs may prescribe under the direction of a Renal physician) in formulary and Renal Specialist Formulary List* as per <a href="#">Local Treatment Protocol</a> . See also page 5 - Updates from previous SMC advice.
<a href="#">Wound Management Formulary</a>	Section 1: Formulary dressings	Aquacel ribbon added
	Section 8: Burns	Chapter review and update.

\* Updates to Specialist Formulary Lists may be delayed this month

## SMC Briefing Note:

[Click here](#) for September Briefing Note

[Click here](#) for October 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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