



Special points of interest for Primary Care

- Prescribing changes in primary care - Erectile dysfunction
- Pioglitazone and insulin - risk of heart failure
- Electronic access to Martindale, Stockley and DTB

SMC advice:

- Botulinum toxin type A injection (Botox®)
- Exenatide injection (Byetta®)
- Sildenafil citrate injection (Revatio®)
- Dalteparin sodium injection (Fragmin®)
- Fosaprepitant dimeglumine infusion (IVEmend®)
- Pazopanib film-coated tablets

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Specialist Lists - update

Stroke, Renal, Palliative Care and Rheumatology specialist lists are all currently in development and should be available in the next couple of months.



Guidelines and Protocols

Denosumab protocol

Denosumab is a human monoclonal antibody, administered subcutaneously once every six months, for the treatment of osteoporosis in post menopausal women at increased risk of fractures. This drug may be useful in patients for whom oral bisphosphonates are unsuitable due to contraindication, intolerance or inability to comply with the special administration instructions and when other oral alternatives, strontium ranelate or raloxifene are unsuitable. Currently denosumab is restricted to hospital only use while the issue of a local primary care fee for administration is negotiated. [Click here](#) for denosumab treatment protocol.

Parathyroid Hormone Protocol - Update

The local medicine treatment protocol for teriparatide and recombinant human parathyroid hormone has been updated in line with the revised template.

For further information [click here](#)

These drugs are recommended in patients:

- who are 65 years and older and have a T-score of -4.0 SD or below, or a T-score of -3.5 SD or below plus more than two fragility fractures, or who are 55 to 64 years and have a T-score of -4.0 SD or below plus more than two fractures

AND

- unable to take bisphosphonates, strontium ranelate, raloxifene or denosumab or have had an inadequate response to the above agents.



Drug Safety Updates

Please follow links:

[Drug Safety Update, Volume 4, Issue 7, February 2011](#)

[Drug Safety Update, Volume 4, Issue 8, March 2011](#)



Drug Safety Updates continued

Pioglitazone and insulin - risk of cardiac failure

The [MHRA Drug Safety Update, Volume 4, Issue 6, January 2011](#), highlights that cases of cardiac failure have been reported when pioglitazone has been used in combination with insulin, especially in patients with risk factors for the development of cardiac failure. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac status occurs. The NHS Tayside Diabetes MCN Handbook advises that pioglitazone use with insulin should only occur in exceptional cases and under close specialist supervision because of the risk of fluid retention. Advice on this has also been added to the [Tayside Area Formulary section 6.1](#).



Prescribing Changes

Sugammadex

Sugammadex (Bridion®) was accepted for restricted use within NHS Scotland for the immediate reversal of rocuronium-induced neuromuscular blockade in Feb 2009. Click here for [SMC advice](#).

Recently the department of anaesthesia presented a case to support limited use of sugammadex for the routine reversal of neuromuscular blockade in a selected group of patients / circumstances. This was approved by the ADTC in Feb 2011 with audit data to be presented to the ADTC in a year's time. Please [click here](#) for further information.

Treatment of Erectile Dysfunction in Patients with Severe Distress

Schedule 2 of Section 17N(6) of the NHS (Scotland) Act 1978 lists drugs that can be provided in general practice only in certain circumstances. This has recently been amended to enable GPs to prescribe drug treatments for erectile dysfunction for men who have been assessed by the relevant consultant and/or advised by the relevant consultant as suffering severe distress as a result of their erectile dysfunction. Refer to NHS Circular 4 PCS(M)(2011) for further information - [CLICK HERE](#)

The Urology Team is currently reviewing the local treatment pathway for patients with erectile dysfunction to incorporate this change and to clarify how the above assessment and advice will be managed in NHS Tayside.



Electronic access to Martindale, Stockley and DTB

Electronic access to two widely used pharmacy textbooks; Martindale-The Complete Drug Reference and Stockley's Drug Interactions are no longer available through electronic books via the Knowledge Network using an individual Athens password. Stockley's Drug Interactions has been re-instated and is available only through [Medicines Complete](#) via ATHENS login. Martindale is no longer available through Medicines Complete using an ATHENS password.

Martindale is now available via www.thomsonhc.com. Username- nhshed. Password- scotland. On some sites it can also be accessed via 'Return to Athens login' on right hand side of the screen. Enter drug name in the search field. Information for Micromedex will be displayed first. Martindale access is usually below this.

This does not affect access for community pharmacists to both Martindale & Stockley from Medicines Complete - via the Community Pharmacy Scotland website.

The Drug & Therapeutics Bulletin (DTB) - Free access to DTB is now available via [The Knowledge Network](#) via ATHENS login or directly from the [Drug and Therapeutics Bulletin website](#) via ATHENS login.

Medicine	Indication	Local recommendation category	Comments and useful links
Adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) - Full submission	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present.	Not recommended	SMC advice
Botulinum toxin type A 50 unit, 100 unit and 200 unit powder for solution for injection (Botox®) - 2nd Resubmission	Focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults.	Hospital only - Centre for Brain Injury Rehabilitation	SMC advice SPC link (50 units) SPC link (100 units) SPC link (200 units)
Botulinum toxin type a (Bocouture®) - Non-submission	Temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at frown, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.	Not recommended	SMC advice
Dalteparin sodium, 5,000IU/0.2mL, 7,500IU/0.3mL, 10,000IU/0.4mL, 12,500IU/0.5mL, 15,000IU/0.6mL, 18,000IU/0.72mL solution for injection. (Fragmin®) - Full submission	Extended treatment of symptomatic venous thromboembolism (VTE) and prevention of its recurrence in patients with solid tumours.	GPs may prescribe under the direction of the Oncology or Haematology Clinic	SMC advice SPC link SIGN 122 (Prevention and management of VTE)
Exenatide, 5 or 10 micrograms, solution for injection, pre-filled pen (Byetta®) - Full submission	Treatment of type 2 diabetes mellitus in combination with thiazolidinediones with or without metformin in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.	Formulary - restricted use Restricted to use, in patients with eGFR 30-60 mL/min who require a third-line antidiabetic agent. GPs may prescribe under the direction of the diabetic clinic.	SMC advice SPC link <i>Liraglutide is preferred over exenatide in patients with eGFR>60 mL/min</i>
Fosaprepitant dimeglumine 150 mg powder for solution for infusion (IVEmend®) - Abbreviated submission	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults. IVEmend 150 mg is given as part of a combination therapy.	Pending* OHMMG decision	SMC advice
Pazopanib 200mg, 400mg film-coated tablets (Votrient®) - Full submission	First-line treatment of advanced renal cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease.	Pending* OHMMG decision SMC restriction: first line treatment of advanced RCC	SMC advice
Sildenafil citrate 0.8mg/mL solution for injection (Revatio®) - Abbreviated submission	Treatment of patients with pulmonary arterial hypertension who are currently prescribed oral sildenafil and who are temporarily unable to take oral medicine, but are otherwise clinically and haemodynamically stable.	Hospital only Under the direction of the Scottish Pulmonary Vascular Unit or the Scottish Adult Congenital Cardiac Service	SMC advice SPC link
Vinflunine ditartrate 25mg/mL concentrate for solution for infusion (Javlor®) - Full submission	Monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract (TCCU) after failure of a prior platinum-containing regimen.	Not recommended	SMC advice

* '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
Denosumab 60mg solution for injection in pre-filled syringe (Prolia®) (651/10) - Full submission	Osteoporosis in postmenopausal women at increased risk of fractures.	Hospital only - Bone Clinic or Medicines for the Elderly Restricted to patients with a bone mineral density (BMD) T-score < -2.5 and \geq -4.0 for whom oral bisphosphonates are unsuitable due to contraindication, intolerance or inability to comply with the special administration instructions and when other oral alternatives (strontium ranelate or	SMC advice SPC link Local protocol Denosumab may be considered in patients with T-scores of less than -4.0, beyond the licence, on the advice of the osteoporosis clinic.



Tayside Area Formulary (TAF) Updates - Mar/Apr 2011

TAF Section	Drug(s)/topic	Changes
6.1	Pioglitazone	Information added on risk of heart failure when pioglitazone is combined with insulin. Link to Drug Safety Update, Volume 4, Issue 6, January 2011 inserted.
	Liraglutide and exenatide	Note added that if eGFR>60mL/min liraglutide is preferred over exenatide and exenatide is for use in patients with eGFR 30-60mL/min. Minor change to wording to incorporate SMC advice on exenatide that it may be used in combination with metformin and a thiazolidinedione as a third-line pre-insulin treatment option for patients with eGFR 30-60mL/min.
6.6	Drugs affecting bone metabolism	Links to National Osteoporosis Guideline Group (NOGG) Pocket Guide for Healthcare Professionals and NICE TA161 inserted. Removal of notes on use of alendronate and risedronate in patients with pre-existing upper GI problems and glucocorticoid induced osteoporosis. Addition of information on use of bisphosphonates in renal impairment. Addition of information on increased risk of atypical fractures with bisphosphonates and link to Drug Safety Update Volume 2 Issue 8, March 2009 inserted. Removal of link to Drug Safety Update, July 2008 on association with AF and bisphosphonates. Denosumab (Prolia®)* added to formulary as a prescribing note along with a link to the local protocol . Link to local protocol on teriparatide and parathyroid hormone updated to new version.
9.4	Oral nutrition	Removal of Enmix Plus Commence as a starter pack option as discontinued. Ensure Plus Commence remains as the recommended starter pack. Change to layout of section with supplement drinks now listed in a table format.

* SMC accepted medicine

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