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Guidance for Prescribers and Dispensers of Anti-resorptive or Anti-angiogenic Drugs

Scottish Dental Clinical Effectiveness Programme

Patients who are taking anti-resorptive (e.g. alendronic acid, risedronate, pamidronate) or anti-angiogenic drugs (e.g. sunitinib, bevacizumab, aflibercept) have a small risk of developing medication-related osteonecrosis of the jaw (MRONJ). This condition may be more prevalent in patients who have dental procedures which impact on bone, for example dental extractions.

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To help dentists provide appropriate dental care for this patient group, new guidance on the Oral Health Management of Patients at Risk of Medication-related Osteonecrosis of the Jaw was published in March 2017 by the Scottish Dental Clinical Effectiveness Programme (SDCEP). The guidance provides recommendations, advice and information to help dental practitioners manage the routine dental care of patients prescribed drugs associated with medication-related osteonecrosis of the jaw (MRONJ). This guidance is an update to the previous SDCEP Oral Health Management of Patients Prescribed Bisphosphonates guidance.

Cost effective Oral
Nutritional Supplements
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The guidance recommends that dental practitioners assess a patient's risk of MRONJ based on their medical condition, type and duration of drug therapy and any other complicating factors. This requires the dental practitioner to be aware that the patient is taking one or more of these medications and to also know details of the patient's medical condition, duration of drug treatment and any other medications that the patient may be taking. The guidance also recommends that before commencement of treatment with these drugs or as soon as possible thereafter, the patient should undergo a thorough dental assessment, with remedial dental treatment where required.

Nystatin dose changes

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Prescribers and dispensers of anti-resorptive or anti-angiogenic drugs can play a key role in ensuring that patients are aware of the type of medication they are taking and the need to inform their dentist about their medical condition and the drugs they are taking. The new guidance recommends that prescribers and dispensers of these drugs advise patients at the commencement of treatment that there is a risk of medication-related osteonecrosis of the jaw (MRONJ) and that they should make an appointment for a dental examination as soon as possible to ensure that they are dentally fit. They should also be advised to tell their dentist about the medication they are taking. Patient information leaflets are available to assist in this communication. The guidance also recommends that cancer patients should preferably undergo a thorough dental assessment, with remedial dental treatment where required, prior to commencement of the drug therapy. The guidance advises that dentists may in some cases need to seek clarification of a patient's health conditions or medications from the patient's GP or medical specialist.

An information sheet detailing the recommendations which are specific to prescribers and dispensers is available for download from the SDCEP website, www.sdcep.org.uk. The full guidance and patient information leaflets can also be downloaded from this website.

SDCEP is an initiative of the National Dental Advisory Committee and operates within NHS Education for Scotland. NICE has accredited the process used by the Scottish Dental Clinical Effectiveness Programme to produce its Oral Health Management of Patients at Risk of Medication-related Osteonecrosis of the Jaw guidance. Accreditation is valid for 5 years from 15 March 2016. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For further information go to www.sdcep.org.uk, email scottishdental.cep@nes.scot.nhs.uk or telephone 01382 425751.

Valproate and developmental disorders: Reminder for patient review and further consideration of risk minimisation measures

Babies born to mothers who take valproate-containing medicines during pregnancy have a 30-40% risk of developmental disability and a 10% risk of birth defects. Despite communications from the MHRA to prescribers in January 2015 and February 2016 on the magnitude of this risk and the actions to be taken, there is evidence that as many as 1 in 5 women taking valproate are still not aware of the risk. A Patient Safety Alert has been issued asking all organisations to undertake systematic identification of women and girls taking valproate, whether for the licensed use or an off-label use.

Current Advice for healthcare professionals from the MHRA

- do not prescribe valproate medicines for epilepsy or bipolar disorder in women and girls unless other treatments are ineffective or not tolerated; migraine is not a licensed indication
- ensure women and girls taking valproate medicines understand the 30-40% risk of neurodevelopmental disorders and 10% risk of birth defects and are using effective contraception
- valproate use in women and girls of childbearing potential must be initiated and supervised by specialists in the treatment of epilepsy or bipolar disorder.

Communication materials and resources have been released to support discussion of the risks with women and girls of childbearing potential who take valproate. ([LINK](#))

In March 2017, the European Pharmacovigilance Risk Assessment Committee (PRAC) initiated a further review to look at the use of valproate-containing medicines in women and girls of childbearing potential. The Committee will consider whether these medicines require further restrictions of use due to their very high risk of causing developmental disorders and congenital malformations to unborn babies and evidence of continued use in pregnancy. Additionally, the European Medicines Agency has decided to organise a public hearing later this year as part of their review of valproate.

A short-life working group has also been proposed for Grampian to look into this issue further. In the meantime prescribers are advised to identify all their female patients of childbearing potential currently receiving valproate containing medicines and ensure they have been advised of the risk and that this has been documented in patient records.

Cost effective Oral Nutritional Supplements (ONS) prescribing

Carole Noble, Dietetic Prescribing Advisor

There is a significant difference in the cost of several of the more commonly prescribed Oral Nutritional Supplements (ONS). Complan Shake[®] is NHS Grampian's first line recommended prescribed ONS (Complan Shake[®] is a powder supplement, made up with whole milk). However, it will not be suitable for everyone. Where a ready-to-drink ONS is required the products listed below, in bold, should be first line choices. These products represent better value for money than some of the other commonly prescribed ready-to-drink ONS and have been shown to be well tolerated in different patient groups.

Ensure Plus[®] Milk shake/yogurt/ savoury
Ensure Compact[®]
Ensure Juce[®]

While NHS Grampian will make savings on the current usage of these products, additional savings can be made by switching from some competitor products. The table below lists some of the comparative prices.

Price Comparison

Ensure Plus[®] milkshake/yogurt/savoury - £1.12/bottle	Fortisip [®] - £1.40/ bottle Fresubin Energy [®] - £1.40/ bottle
Ensure Compact[®] - £1.35/bottle	Fortisip Compact [®] £1.45/ bottle
Ensure Plus juce[®] £1.97/bottle	Fortijuce [®] - £2.02/ bottle Fresubin Jucy [®] - £1.99/ bottle

All patients requiring an ONS should be referred to the community dietitians as per NHSG guidelines. ([Policy For The Prescribing and Administration Of Oral Nutritional Supplements In Adults By General Practitioners And Primary Care Staff Working Within NHS Grampian.](#))

Nystatin Dose Changes

There has been recent confusion surrounding dose changes to nystatin suspension as dosing advice in both the BNF and Bristol Myers Squibb SmPC had changed. **The MHRA have confirmed that the dosing of nystatin to treat oral candida has now reverted back to the original 1ml, four times.** The BNF, BNF for children and both SmPCs for nystatin suspension (Squibb and Sandoz) are now aligned once again.