GUIDELINES FOR THE PREVENTION AND TREATMENT OF OSTEOPOROTIC FRAGILITY FRACTURES

This document has been revised subsequent to NICE guidance TA160 &161 for the primary and secondary prevention of osteoporotic fragility fractures in postmenopausal women.

INVESTIGATIONS

It is important to exclude secondary causes of bone loss and primary osteoporosis can only be assumed if the following are normal: ESR + FBC + U+E, creatinine + TFT, LFT, Ca, phosphate.

If indicated :- FSH in women, or serum testosterone, LH and SHBG in men, if hormonal status unclear.
Serum paraproteins & urine Bence Jones protein. Lateral thoracic & lumbar spine X-rays. Isotope bone scan. DEXA scan as appropriate.

LIFE STYLE ADVICE

Encourage weight bearing activity (e.g.walking 20 mins/day). **Dietary intake of 1000mg calcium per day – postmenopausal women.** Limit cigarette and alcohol consumption

VITAMIN D

See Separate Guidelines.

CALCIUM & VITAMIN D PREPARATIONS: supplementation should be provided unless clinicians are confident patient is Calcium and Vitamin D replete post fragility fracture

CONTENT	NAME	DOSAGE & COMMENT
Calcium♦ 1000mg & colecalciferol 880iu	**TheiCal-D3 chewable tablets**	One chewed once each day
Calcium♦ 1200mg & colecalciferol 800iu	**Calfovit D3 granules**	One sachet dissolved in water once each day
Calcium♦ 600mg & colecalciferol 400iu	**Adcal-D3 Dissolve**	One tablet dissolved in water twice a day

♦ - Elemental calcium content.

Note

- **All patients expected to require 7.5mg prednisolone equivalent or more for longer than three months should have calcium and Vitamin D preparations, and possibly bisphosphonate therapy.**
- **All people (men or women) over 80 can be assumed to be osteoporotic and would benefit from calcium and Vitamin D preparations (if renal function is adequate and they are not hypercalcaemic).**

APPROVED BY: North East Essex Medicines Management Committee January 2016 **REVIEW DATE: January 2018**
Reviewed by: Paul Byrne, Consultant Rheumatologist (CHUFT) & Sheila Baldwin, Head of Medicines Management (NEE CCG).

PREVENTION OF OSTEOPOROSIS

For secondary prevention, the first choice drug is generic alendronic acid and second choice risedronic acid. Third choice agents for patients intolerant of oral preparations are iv zoledronic acid or sub cut denosumab.

When the above are not tolerated or contraindicated then teriparatide (PTH) could be considered in appropriate patients.
Please note not all products are licensed in men for the recommended indications however evidence supports their use.
It is anticipated that most patients who are intolerant to one oral bisphosphonate will also be intolerant to others. Always use generic alendronic acid as the first line agent.

***Strontium should no longer be used on safety grounds.** *** Ibandronic acid is not recommended for use locally.**

DRUG	INDICATION	DOSAGE
Oral bisphosphonates must be taken at least 30 minutes before the first food, beverage or medicinal product of the day with plain water only (not less than 200 ml or 7 fl.oz.). Other beverages (including mineral water), food and some medicinal products are likely to reduce their absorption. Patients should remain upright and not lie down or bend over for at least 30 minutes after taking the tablets.		
Alendronic acid (generic)	Osteoporosis in post-menopausal women, men over the age of 75 years or at high risk of fracture and steroid induced osteoporosis Continue treatment for a **maximum of 5 years** then stop with regular review of patients	**70mg weekly**
Risedronic acid (generic)	Osteoporosis in post-menopausal women, men over the age of 75 years or at high risk of fracture and steroid induced osteoporosis Continue treatment for a **maximum of 5 years** then stop with regular review of patients	**35mg weekly or 5mg daily (note cost)**
Denosumab (Prolia)	Osteoporosis in post-menopausal women and men over the age of 75 years or at high risk of fracture when intolerant of oral preparations. Consultant initiation and first treatment given in secondary care then transfer to primary care. Continue treatment for a **maximum of 3 years** then stop with regular review of patients	**60mg sub cut once every 6 months**
Zoledronic acid (Aclasta) **Consultant initiation only**	Osteoporosis in post-menopausal women and men over the age of 75 years or at high risk of fracture when intolerant of oral preparations. Continue treatment for a **maximum of 3 years** then stop with regular review of patients	**5 mg in 100 ml ready-to-infuse solution**
Teriparatide (Forsteo) (PTH)	Women aged 65 or over who are intolerant of bisphosphonates or have an unsatisfactory response to them and who have an extremely low BMD or a very low BMD plus multiple fractures plus one or more additional risk factors. (normally, consultant instigation only)	**Daily subcutaneous injection**

Intolerance of bisphosphonates is defined as oesophageal ulceration, erosion or stricture, or severe lower GI symptoms any of which warrants discontinuation of treatment.

For primary prevention, the first choice drug is generic alendronic acid, with risedronic acid as second line. Teriparatide (parathyroid hormone) s/c, zoledronic acid iv and denosumab s/c are not recommended first line due to lack of cost effectiveness, except in severe cases i.e. very low bone density.

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