Gateshead Clinical Commissioning Group

Guideline for the management of osteoporosis in primary care

Implementation date: November 2013

Review date: November 2015

This guideline has been prepared and approved for used within Gateshead in consultation with Gateshead CCG and Secondary Care Trusts.

Approved by:

Committee	Date
Gateshead Medicines Management Committee	9th October 2013
Alliance Medicines Optimisation, Pathways and Guidelines Committee	9th October 2013

Equality & diversity statement: this guideline will aim to be fair to all patients regardless of age, disability, gender, race, sexual orientation, religion/ belief or any other factor that may result in unfair treatment or inequalities in health/ employment.

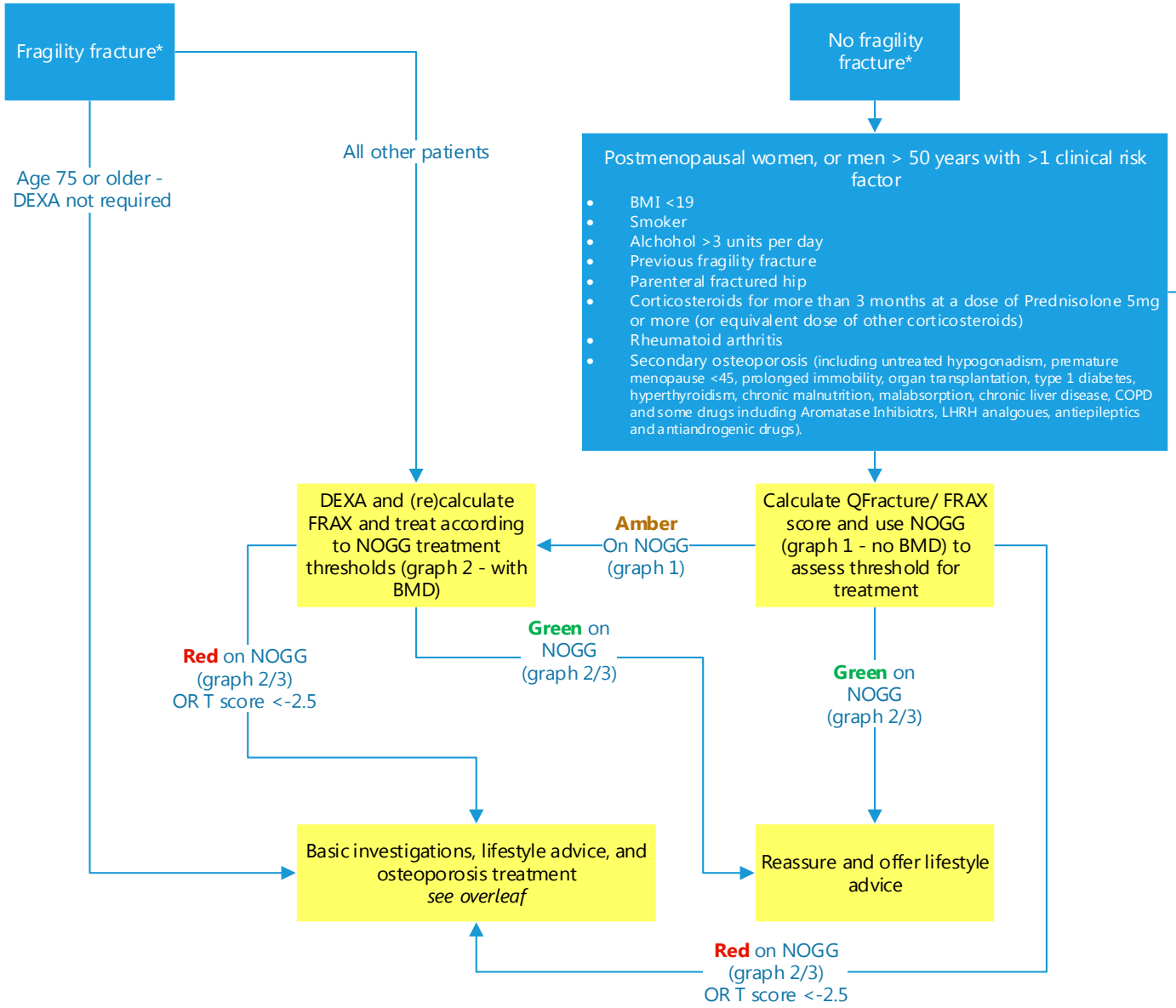
This guideline is not exhaustive and does not override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This guideline should be used in conjunction with the following guidelines:

- NICE TA160
- NICE TA161
- NICE TA204
- NOGG Osteoporosis clinical guideline for prevention and treatment

Full details of contra-indications and cautions for individual drugs are available in the BNF or in the Summary of Product Characteristics (available in the Electronic Medicines Compendium) www.emc.medicines.org.uk

Osteoporosis treatment algorithm



Fragility Fracture is defined as a fracture caused by falling from standing height or lower at walking speed or slower. It also includes vertebral and hip fracture even if there is no history of trauma. Fractures of the skull, facial bones, or digits are not included. The terms ***low trauma fracture*** and ***osteoporotic fracture*** have an identical meaning for the purpose of this guidance.

Patients with inflammatory bowel and coeliac disease

Consider DEXA for patients with inflammatory bowel disease or coeliac disease and **2 or more** of the following BSG criteria:

- Continuing active disease (IBD)
- Persisting symptoms (coeliac disease) despite gluten free diet for >1 year (please review gluten free diet before referring for DEXA – BMD can improve dramatically with adherence to a gluten free diet)
- Weight loss >10%
- BMI <20
- Age >70 years

Patients/ conditions requiring referral to and management in secondary care

- Patients that continue to lose bone on BMD or fracture despite being fully concordant with treatment
- Premenopausal women and those with anorexia
- Men under the age of 75
- Unexpected or unexplained low BMD
- Breast cancer patients on aromatase inhibitors who are unable to tolerate 1st line treatment or continue to loose bone despite being fully concordant with treatment
- Prostate cancer patients on hormone treatments who fracture
- Patients who are at risk of varices and there is a need for IV or SC treatment
- Patients with coeliac or inflammatory bowel disease who meet BSG criteria
- When there is a discrepancy between NOF and LS T scores
- Fracture in Paget's' patients, osteogenisis imperfecta, hyperparathyroid and throtoxicosis
- Vertebral fractures where there is persistent pain two months post fracture, those with difficult pain control, unstable or burst fractures and multiple vertebral fractures

Basic investigations, lifestyle advice, and osteoporosis treatment

Falls assessment and lifestyle advice

- Adequate nutrition, especially with calcium
- Regular weight bearing exercise
- Avoidance of tobacco use and alcohol
- Care home patients, housebound, frail elderly and patients in sheltered accommodation should be considered for calcium and vitamin D therapy.

Click here to access downloadable patient information leaflets from the National Osteoporosis Society.

Osteoporosis treatment

Please refer to the appropriate manufacturers' SPC and/or BNF entry for further information on cautions, contraindications and administration instructions.

1st line – alendronate 70mg once weekly or risedronate 35mg once weekly

To be taken after an overnight fast and 30 minutes before the first food or drink (other than water) of the day or any other oral medicines. Tablets should be swallowed whole with a glass of water while the patient is sitting or standing in an upright position. Patients should not lie down for 30 minutes after taking.

Alendronate is contraindicated in patients with renal impairment (eGFR <35ml/min) and abnormalities of the oesophagus that delay emptying, ability to stand upright for at least 30 minutes and hypocalcaemia.
Risedronate is contraindicated in patient with severe renal impairment and patients with hypocalcaemia.

Patients taking bisphosphonates are at increased risk of developing osteonecrosis of the jaw. Patients with poor dental health should have a dental examination prior to treatment. During bisphosphonate treatment patients should maintain good oral hygeiene, attend for regular routine dental check—ups and report any oral side effects (MHRA/ CHM advice 2009).

Patients should be reviewed after 5 years' bisphosphonate treatment. Please refer to separate guideline for further information.

2nd line choices

The following choices are for **specialist initiation only** in line with the Gateshead formulary

Strontium

Restricted to the treatment of **severe osteoporosis** in postmenopausal women at high risk of fracture and in men at increased risk of fracture due to risk of serious cardiac disorders (MHRA 2013)

Not to be used in patients with ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, a history of these conditions or patients with uncontrolled hypertension. Treatment should be stopped if the patient develops any of these conditions.

Intravenous bisphosphonates

Review patients after 3 years

Teriparatide

Only to be considered by secondary care specialists in line with NICE TA161

Denosumab*

Contraindicated in patients with hypocalcaemia. Patients with pre-existing hypocalcaemia must be corrected prior to initiating denosumab. Vitamin D deficiency/ insufficiency (<50nmol/l) should also be corrected prior to treatment.

Basic investigations

- FBC, CRP, U&Es, LFTs, GGT, Ca, Serum vitamin D and phosphate, TFTs
- ESR – to exclude myeloma
- TTG – marked unexplained osteoporosis and/or suspicion of coeliac disease

Investigations to consider if Secondary cause suspected

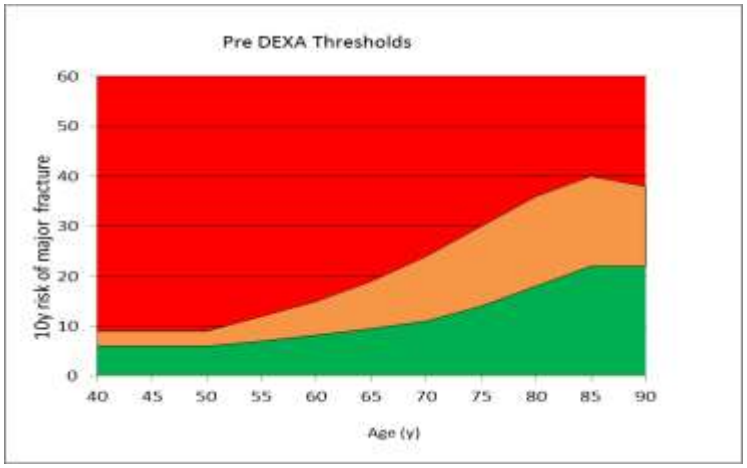
Depending on the results from the basic investigations, consider excluding secondary causes

- PSA – male vertebral or pathological fractures
- PTH – only if serum calcium is abnormal
- Serum/ urine electrophoresis

* a local enhanced service is in development (October 2013) to enable the continuation of denosumab in primary care (October 2013). Until such a time as the LES is in place secondary care will be responsible for initiating and continuing denosumab treatment.

Graph 1

Use this graph prior to determining the need for referral for DEXA scan



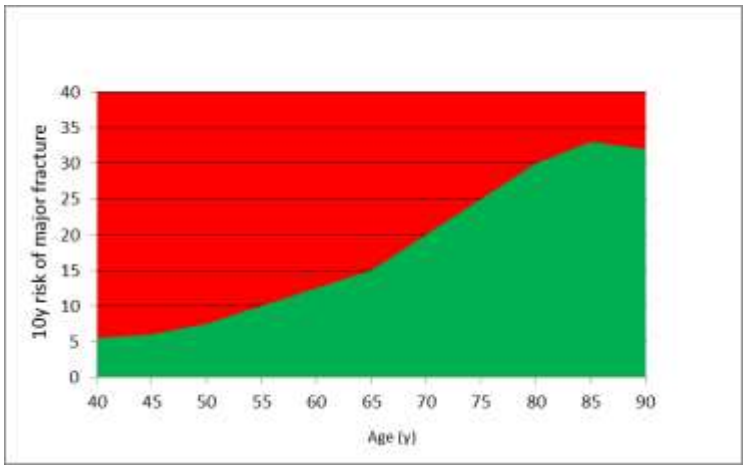
Treat – DEXA not required

Refer for DEXA

DEXA not required
Lifestyle advice and reassure

Use either or both of these graphs to determine when to continue treatment and when to recommend a drug holiday

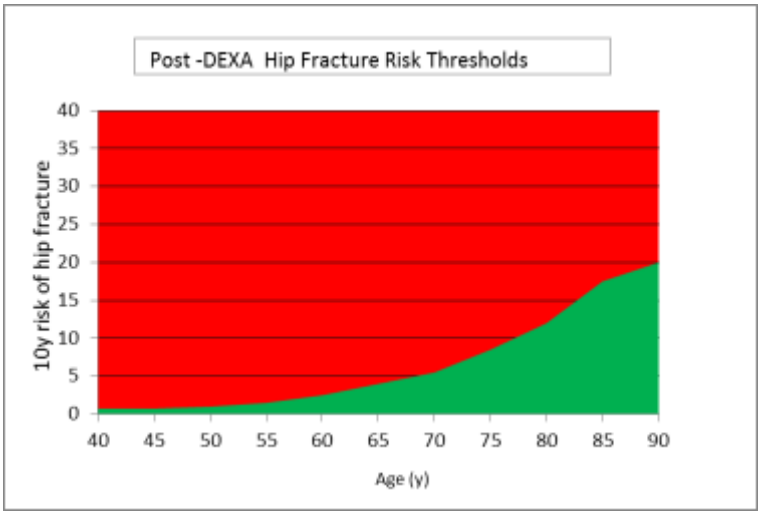
Graph 2 – 10yr risk of major fracture (with BMD)



Treatment recommended

Lifestyle advice and reassure

Graph 3 – 10yr risk of hip fracture (with BMD)



Treatment recommended

Lifestyle advice and reassure

To ensure an adequate review, the following must be discussed:

Check Adherence: is the patient adherent with bisphosphonate and calcium and vitamin D?

- Ensure the patient is aware of the risks of non-adherence
- Do not refer the patient for a DEXA if the patient has been significantly non-adherent (clinical judgement required as there is no evidence relating to a specific % adherence)

Taking correctly: Is the patient able to comply with specific instruction to take bisphosphonates?

- Consider water volume, should be not less than 200mls for alendronate and 120mls for risedronate
- Remain in the upright (sitting or standing) position for 30 mins after taking a bisphosphonate
- Taken at least 30 mins before food and any other medication, preferably on rising in the morning for risedronate or alendronate and 2 hours before and after food for etidronate

Adverse Effects: Is the patient suffering from any adverse effects?

- Gastrointestinal effects (e.g. dyspepsia or reflux despite taking as per administration instructions) Complying with the administration directions can help reduce GI adverse effects. GI side-effects are common in the first month of treatment but will reduce significantly from month 2.
    - If GI side effects intolerable on alendronate, consider switching to risedronate as Prescription Event Monitoring studies suggest gastrointestinal side effects are lower (note these are observational studies and therefore, may be subject to surveillance bias, therefore difference in side-effects is not proven)
    - 32.3 consultations for GI adverse effects per 1000 patient months for alendronate and 26.9 for risedronate in month 1 reducing to 10.9 for alendronate and 8.1 for risedronate in month 2
- If problems with **swallowing** oral bisphosphonates, consider alendronate liquid
- Has developed upper oesophageal pathology during treatment (e.g. stricture, achalasia, Barrett's) on bisphosphonates; **STOP** the bisphosphonate and refer for consideration of other bone sparing agents

References

1. NICE Osteoporosis – primary prevention (TA160) (January 2011)
2. NICE Osteoporosis – secondary prevention including strontium ranelate (TA161) (January 2011)
3. NICE Osteoporotic fractures – denosumab (TA204) (October 2010)
4. NOGG Osteoporosis. Clinical guideline for prevention and treatment (May 2013)
5. Bone and Tooth Society of Great Britain. National Osteoporosis Society. Royal College of Physicians. Glucocorticoid-induced osteoporosis: guidelines for prevention and treatment. London: Royal College of Physicians (2002)
6. British Society of Gastroenterology. Guidelines for osteoporosis in inflammatory bowel disease and coeliac disease (2007)