Management guidelines for the primary and secondary prevention of osteoporosis related fractures in postmenopausal women and men aged > 50 yrs

Guidelines exclude glucocorticoid and aromatase inhibitor induced osteoporosis risk*
Women aged < 50 and men aged < 65 should be referred to a specialist clinic

- Post menopausal women and men >50 with a new or prior fragility fracture
  - Post menopausal women + men over 75 (1)
    - BMD at hip or spine < -2.5
      - Exclude secondary causes (2)
        - Lifestyle advice (4)
        - Co-prescribe calcium/D3 unless replete
        - Consider falls service assessment
        - Advise treatment (5)
        - 1st Line ALENDRONATE 70mg WEEKLY
    - BMD at hip or spine -1 to -2.5
      - Consider FRAX in individuals with multiple clinical risk factors - www.shef.ac.uk/FRAX (3)
      - Reassure
        - Lifestyle advice
        - Consider follow-up and repeat DXA

- Post menopausal women and men >50 without fragility fracture but one or more relevant clinical risk factors (6)
  - Perform DXA (1)
    - BMD at hip or spine < -2.5
      - Consider need for treatment (7)

1) DXA in over 75 year old men and women

Though NICE considers this unnecessary in women it may help to aid compliance or identify those at very low or very high risk in both sexes and inform management decisions.

2) Investigations

Men are more likely to have secondary osteoporosis: it is recommended that men <65yrs and women <50 years are referred to a specialist clinic for further investigation.

All Patients:
- FBC, PV desirable (If PV raised or suspicion of myeloma, measure serum paraproteins and urine for Bence Jones protein)
- Bone and liver function tests (Ca, P, Alk phos, albumin, ALT)
- Serum creatinine

Additional tests if indicated:
- Serum TSH.
- Serum 25 OH VitD (and PTH if hypercalcaemic or renal impairment)
- Serum testosterone, LH and SHBG, PSA (men)
- TT Glutaminase
- Lateral thoracic and lumbar spine X rays
- Follow-up DXA is not normally necessary in compliant patients on treatment or those without an uncontrolled secondary cause
- Further imaging may be appropriate- consider discussion with specialist

3) FRAX

Individuals with additional clinical risk factors and a T-score in the osteopenic range may have a fracture risk greater than that associated with osteoporosis and a fragility fracture. Consideration of treatment, follow-up or referral may be appropriate, especially in the presence of a vertebral body fracture. The FRAX score may help here to determine 10 year fracture risk and inform clinical decision making. Caution is advised in using the NOGG intervention threshold linked to FRAX as it may lead to over-treatment of younger individuals and under-treatment of older individuals.

4) Lifestyle measures

Include weight-bearing exercise advice, adequate nutrition optimising calcium and vitamin D3 intake, avoidance of tobacco, sensible drinking, safe sun exposure.

5) Treatment

- Advise periodic review of adherence to therapy.
- Consider referral or check concordance if patient sustains a fracture on therapy (although treatment does not abolish fracture risk)
- Refer if severe renal impairment (Creatinine clearance <30-35ml/min)
- Calcium 1 – 1.2 gram + cholecalciferol 800 IU daily unless confident patient is replete
- 1st Line RISEDRONATE 35 mg WEEKLY if alendronate not tolerated, and no contraindications to oral bisphosphonate

If ORAL BISPHOSPHONATES not tolerated or contraindicated

- DENOSUMAB 60mg s/c monthly. NICE TA 204 has given a positive recommendation to denosumab if bisphosphonates are not tolerated or contraindicated in secondary prevention of osteoporotic fracture in post menopausal women without any other restrictions. Refer to specialist for initiation
- STRONTIUM RANELATE 2 gram (at bed-time 2 hours after food) may be suitable. Additional evidence for primary prevention of fragility fractures in women > 80 years, and for women aged > 75 years with a previous fragility fracture. Strontium is not licensed for men
- INTRAVENOUS BISPHOSPHONATES if difficulties with compliance. These are also licensed for use in men and steroid induced osteoporosis.
- HRT may be appropriate in menopausal women before age 50 but not advised if risk of VTE
- RALOXIFENE 60mg DAILY (for postmenopausal women with vertebral osteoporosis if intolerant to bisphosphonates or strontium) Raloxifene is not licensed for men and is not advised if risk of VTE
- TERIPARATIDE should be considered if bisphosphonates or strontium not tolerated or CI, or failed on treatment, and if 65+ with a T-score of -4.0 or -3.5 plus > two fractures, or who are aged 55–64 years with a T-score of -4 SD plus > two fractures- Refer to Specialist for initiation

Safety concerns may suggest a break in therapy after 5 years but those with a high risk (Vertebral fracture, BMD still in the osteoporotic range, fracture on treatment, underlying inflammatory condition, those at high risk of falls etc.) may benefit from treatment up to ten years, or even longer. Patients require full counselling as to the relative risks of continuing or discontinuing therapy as well as the risks of fracture even if they continue on treatment.

6) Clinical Risk factors

NICE recognises two classes of risk factor though there are many others that increase fracture risk.

For fracture: For low BMD
- Parental hip fracture BMI < 22 kg/m2
- Alcohol intake > 4 units/day Medical conditions (e.g. Crohn’s disease)
- Rheumatoid arthritis Conditions causing prolonged immobility
- Untreated premature menopause

7) Primary Prevention

NICE guidelines suggest treatment may be indicated in the presence of a T score worse than -2.5 if
- >70 ≥ with 1 CRF of either type described in box 6
- 65-70 with 1 CRF for fracture
- <65 with 1 CRF for fracture and 1 CRF for low BMD
- > 75 with 2 or more CRFs of any type without BMD measurement

As described in box 3, treatment outside NICE guidance may be indicated for individuals with high 10 year fracture risk as determined using the FRAX score. In this situation BMD estimation is recommended to refine risk. Caution is recommended when using the NOGG intervention threshold linked to FRAX as it may lead to over-treatment of younger individuals and undertreatment of older individuals.