Osteoporosis management guidelines for adults in Sunderland

**SECONDARY PREVENTION**

- Fragility fracture (Age ≥ 50)
  - Vertebral fracture
  - Hip fracture
  - Other fractures

- DXA not appropriate:
  - Age >90
  - Co-morbidity limiting attendance
  - Unable to comply physically or cognitively

- Suitable for oral bisphosphonate?
  - Yes
    - Severe SPINAL Osteoporosis (secondary care diagnose as per NICE guidelines)
  - No
    - Zoledronic Acid/Denosumab (Ensure Ca²⁺ & Vit D replete)
      - Oral Bisphosphonates (increase Ca²⁺ & Vit D supplements)
      - Teriparatide (Only 2° care initiation) (Max. 24 months)

- Intolerant or poor response
  - Review after 3 years & reassess
  - Review after 5 years & reassess

- Oral Bisphosphonates increase Ca²⁺ & Vit D supplements
  - Reassess 3 yrs +DEXA
  - Reassess after 5 years

**PRIMARY PREVENTION**

- Clinical risk factors (Age ≥50)
  - Fracture risk assessment (FRAX and/or QFracture)
  - 10-year risk ≥ 10% (any fracture)
  - DXA

- Very strong clinical risk factors (Age < 50) Refer notes
  - Osteopenia -1.0>T>-2.0
  - Normal T ≥ -1

- Osteopenia 2.0>T>-2.5
  - Oral Bisphosphonates increase Ca²⁺ & Vit D supplements
  - Telephone enquiry at 20 weeks by Health professional about compliance with oral bisphosphonates
  - Reassess after 5 years

- Osteoporosis T ≤ -2.5
  - Oral Bisphosphonates increase Ca²⁺ & Vit D supplements
  - Telephone enquiry at 20 weeks by Health professional about compliance with oral bisphosphonates
  - Reassess 3 yrs +DEXA

**Key:**
1. Refer notes below
2. Criteria for poor response:
   - 2 or more fragility fracture on treatment
   - 1 fracture >4 % decline in BMD in 2 years on treatment
   - BONE MARKERS remain raised (done only by bone clinic)
3. Consider repeat DEXA in 3-5 years to assess treatment response.
4. Treatment threshold is usually T-2.5, or T-2.0 (if FRAX >20/5, or age>65yrs and previous fragility fracture)
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**FRAX categories:**

<table>
<thead>
<tr>
<th>Percentage 10 years risk of Major osteoporotic fracture /Risk of Hip fracture</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 20 /5</td>
<td>High risk</td>
</tr>
<tr>
<td>10-19/3-5</td>
<td>Medium risk</td>
</tr>
<tr>
<td>&lt; 10/3</td>
<td>Low risk</td>
</tr>
</tbody>
</table>

(Link to calculate FRAX: https://www.shef.ac.uk/FRAX/tool.jsp)

**Investigations required:**

| For ALL: |  
|-------------------------------------------------|-------------|
| Baseline pre-therapy blood tests                | Bone profile, Vitamin D (consider in high risk patients), Renal function (if eGFR <35 avoid alendronate; avoid Risedronate if eGFR < 30mL/min), TSH |
| Additional Work up for secondary Osteoporosis*  | LH, FSH, Oestradiol (women), testosterone (men), Prolactin, TFT, Calcium, PTH, TTG (Coeliac), Serum/urine electrophoresis |

For MEN and PREMENOPAUSAL WOMEN:

<table>
<thead>
<tr>
<th>Women &lt; 50 years of age</th>
<th>If deemed high risk with underlying secondary pathology consider referral to bone clinic for full assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men &lt;75 years of age</td>
<td>Risk stratify with FRAX scores, consider individualised management plan and Bone clinic referral. N.B in men with suspected osteoporosis consider using the female reference range to calculate adjusted T score at femoral neck (treatment threshold T score&lt;-2.5) – available via FRAX.</td>
</tr>
</tbody>
</table>

**Steroid induced osteoporosis guidance:**

For steroid induced osteoporosis, refer to RCP guidelines. They are available at https://cdn.shopify.com/s/files/1/0924/4392/files/glucocorticoid-induced-osteoporosis-guideline.pdf?2801907981964551469

**Guidance for vitamin D deficient high risk patients:**

For vitamin D deficient ‘high risk’ patients, follow NOS guidance. NOS guidance is available at https://www.nos.org.uk/document.doc?id=1352 Treat vitamin D deficiency (25(OH)D3<25) with 20,000 units cholecalciferol twice weekly for seven weeks (check serum calcium at 4 weeks) and continue maintenance cholecalciferol 800 units.
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Treatment options:

1) Oral Bisphosphonates:
Alendronic acid 70mg weekly/ Risedronate 35mg weekly/ Ibandronic acid 150 mg/monthly (only licensed for post-menopausal women). Alendronic acid is the first line oral agent as per NICE/BNF/Sunderland joint formulary. Patient to try at least 2 different oral bisphosphonate before switching to IV/sc. Binosto (effervescent alendronic acid) may be used for patients who have tried both alendronate and risedronate tablets and are intolerant of both (i.e. as a third oral option before IV zoledronate), or for patients who can't swallow instead of alendronate liquid.

^Usual treatment duration of *Alendronic acid is 5 years. Patients should then be reviewed and reassessed. 10 Years treatment may be considered in high risk patients

2) IV Bisphosphonate:
Zoledronic acid 5 mg once yearly infusion for 3 years- in intolerance/poor response to oral bisphosphonates. Ensure Vitamin D replete prior to IV bisphosphonate therapy.

^ Usual treatment duration Zoledronic acid is 3 years. Patients should then be reviewed and reassessed. (Bone clinic referral required from primary care)

NB Rare complications of bisphosphonates include: osteonecrosis of the jaw ONJ (incidence 1 in 10,000 per annum) and atypical femoral fracture AFF. They are associated with prolonged treatment duration.
Repeat BMD should be considered 3-5 years after starting bisphosphonates. Treatment may be stopped after 5 years if bone density is stable or improved and no fractures.
Bone density decreasing more than 4% from baseline is an indication to re-evaluate the patient and consider changing or adding therapy. Patients at very high risk of vertebral fracture may benefit from continuing treatment beyond 5 years (e.g. patients with low BMD, prevalent vertebral fracture, patients on long term steroids and patients over 75 years). If in doubt please refer to Bone clinic

3) Denosumab: (bone clinic referral required):
60 mg subcutaneous injections six monthly for 3 years initially then a further 2 yrs if necessary -consider for intolerance/poor response to oral bisphosphonates. Denosumab is an “amber” drug i.e. initiated in secondary care by a specialist with shared monitoring in primary care according to agreed protocol.

4) Strontium
Strontium ranelate is no longer available. Raloxifene or calcitriol may be prescribed under the bone clinic, but these treatments are considered less effective. They may be used 4th line if bisphosphonates/denosumab are unsuitable and the patient does not meet criteria for Teriparatide. However, the use of these medications (Raloxifene or calcitriol) is non formulary.

5) Severe Osteoporosis: Consider Teriparatide (bone clinic referral required):
2 or more spinal fractures despite treatment with bisphosphonates and refer to NICE guidelines (TA 161) on severe osteoporosis.

NB Consider calcium and vitamin D supplements in elderly patients and/or patients where dietary intake is deemed insufficient. Measure vitamin D in patients with high risk of deficiency.

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### Risk Factors

The risk of fractures in younger women (<50) who do not have clinical risk factors is likely to be very low. NICE recommends assessment of fracture risk in this group in the presence of major risk factors (previous fracture, oral or systemic glucocorticoid use, hazardous alcohol intake, family history of fracture, low BMI, history of falls and causes of secondary osteoporosis). The presence of any of the non-modifiable factors, diseases or use of drugs listed below is associated with an increased risk of fragility fracture and individuals over the age of 50 should be considered for fracture risk assessment.

<table>
<thead>
<tr>
<th>Non-modifiable risk factors:</th>
<th>Modifiable risk factors:</th>
<th>Co-morbidities:</th>
<th>Pharmacological risk factors:</th>
</tr>
</thead>
<tbody>
<tr>
<td>gender</td>
<td>cigarette smoking</td>
<td>cystic fibrosis</td>
<td>anticoagulants (uncertain role)</td>
</tr>
<tr>
<td>age</td>
<td>alcohol consumption (&gt; 2 drinks/day)</td>
<td>epilepsy</td>
<td>antidepressants</td>
</tr>
<tr>
<td>body size (height and weight)</td>
<td>low BMI &lt;18.5</td>
<td>diabetes</td>
<td>anticonvulsants</td>
</tr>
<tr>
<td>ethnicity (Caucasian and Asian women)</td>
<td>oestrogen deficiency (age &lt; 45 years)</td>
<td>RA and SLE</td>
<td>antipsychotics (uncertain role)</td>
</tr>
<tr>
<td>family history of fracture(s)</td>
<td>bilateral oophorectomy</td>
<td>IBD and malabsorption</td>
<td>aromatase inhibitors</td>
</tr>
<tr>
<td>personal past history of fracture(s)</td>
<td>prolonged premenstrual amenorrhoea (&gt;1 year)</td>
<td>Endocrine diseases, e.g. primary</td>
<td>depotmedroxyprogesterone</td>
</tr>
<tr>
<td>history of fracture(s) in first-degree relative(s)</td>
<td>lifelong low Ca²⁺ intake</td>
<td>hyperparathyroidism, Thyrotoxicosis</td>
<td>GnRH agonists</td>
</tr>
<tr>
<td>menopause</td>
<td>impaired eyesight despite correction</td>
<td>chronic liver disease</td>
<td>antipsychotics</td>
</tr>
<tr>
<td>menstrual history</td>
<td>recurrent falls</td>
<td>Alzheimer's disease</td>
<td>antidepressants</td>
</tr>
<tr>
<td></td>
<td>inadequate physical activity</td>
<td>Parkinson's disease</td>
<td>anticonvulsants</td>
</tr>
<tr>
<td></td>
<td>frailty/poor health</td>
<td>multiple sclerosis (MS)</td>
<td>anticoagulants</td>
</tr>
<tr>
<td></td>
<td>inadequate sun exposure</td>
<td>stroke</td>
<td>anticoagulants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>chronic kidney disease (CKD)</td>
<td>anticoagulants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>asthma</td>
<td>anticoagulants</td>
</tr>
</tbody>
</table>

### Lifestyle advice

Includes smoking cessation, reduction of alcohol consumption, weight-bearing exercise, adequate dietary calcium intake, supplementary calcium and/or vitamin D if necessary, and daily 15-minutes sun exposure (note; high calcium intake may decrease risk of atherosclerosis if achieved without supplements. Calcium supplement use may increase risk of coronary artery calcification)

### Patient information: Patients should be provided with information on osteoporosis medications, (especially ONJ risks and AFF risks with bisphosphonates). Patient information can be found at:

https://www.nos.org.uk/

http://www.arthritisresearchuk.org/arthritis-information/conditions/osteoporosis.aspx

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