NHS Surrey treatment Guidelines for osteoporosis in Adults.

Background

Osteoporosis is a condition characterised by a reduction in bone mass density increasing the risk of fracture. Fractures occur most commonly in the hip, spine and wrist. Vertebral fractures due to osteoporosis can cause loss of height, curvature of the spine and chronic back pain. One in three women and one in twelve men over 50 are affected by osteoporosis and almost half of all women experience an osteoporotic fracture by the time they reach the age of 70.¹

In October 2008 NICE produced TA160 and TA161 for the primary and secondary prevention of osteoporotic fractures. This guidance is restricted to postmenopausal women with osteoporosis as defined by a bone mineral density T-score of ≤-2.5, and does not include men with osteoporosis or individuals treated with glucocorticoids. Several recently introduced interventions, including ibandronic acid and zoledronic acid (and more recently denosumab), are not included in the guidance. The National Osteoporosis Guideline (NOGG) was launched in October 2008 to address these deficits. It is endorsed by many scientific and professional organizations including the National Osteoporosis Society and the Royal College of Physicians.

Areas of agreement between NICE and NOGG include recommendations to treat elderly postmenopausal women with a fragility fracture and the use of generic alendronate as a first line option. There is also agreement that bone mineral density measurements may be useful in reaching treatment decisions in younger postmenopausal women with a fragility fracture. However, whereas NICE requires a T-score ≤-2.5 in most women for either primary or secondary prevention, NOGG recognises the added contribution of independent clinical risk factors to fracture prediction and recommends the use of the WHO-supported fracture risk algorithm FRAX®.

Many cost-effectiveness studies of bone-sparing therapy use the Fracture Risk Assessment tool (FRAX®) http://www.shef.ac.uk/FRAX/ to identify fracture risk thresholds where drugs become cost effective. FRAX combines the major risk factors of age, fracture history and BMD with parental hip fracture, rheumatoid arthritis, alcohol, smoking and chronic disease history to calculate 10-year absolute risk of major osteoporotic fracture and hip fracture. This absolute risk is deemed more appropriate than relying on single risk factors.

In addition, NICE guidance for second line options demands different combinations of bone density and risk factors for different treatments which is complicated to operate in a primary care setting.

In order to provide comprehensive and practical guidance for the management of osteoporosis in primary care setting, the following guidelines suggest a combination of NICE and NOGG that retains the main principles of NICE guidance but incorporates the greater workability of NOGG. It also incorporates NOGG guidance for men with osteoporosis, individuals treated with glucocorticoids, and the use of more recently introduced interventions.

¹ National Service Framework for Older People, Department of Health, 2001
NHS Surrey treatment Guidelines for osteoporosis in Adults

Primary care

Postmenopausal women >75yrs

Fragility fracture

Postmenopausal women < 75yrs or men > 50yrs

No Fragility fracture

Osteoporosis treatment

- Falls assessment
- Lifestyle advice
- Calcium and Vitamin D supplement (Adcal D3 preferred NHS Surrey product)
- Post menopausal women: Alendronic acid 70mg weekly
  - If intolerant consider Risedronate 35mg weekly
  - If intolerant or bisphosphonate contraindication Strontium ranelate 2g daily

Based on NICE technology appraisal guidance 160 Osteoporosis - Primary Prevention and 161 Secondary prevention of osteoporotic fragility fractures in postmenopausal women (updated Jan 2011)
http://guidance.nice.org.uk/TA161/Guidance/pdf/English

- For men and prevention/treatment of corticosteroid induced osteoporosis refer to table for summary of licensed indications

Secondary care

Refer For:
- Patients unable to tolerate/ respond to oral bisphosphonate and / or strontium treatment.
- Osteoporosis with complex medical problems
- Fragility fractures due to other bone disease

Secondary care treatment options:
The following are red drugs in Surrey PCT refer to www.app.surreyhealth.nhs.uk/tls

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoledronic acid</td>
<td>5mg annual IV infusion</td>
</tr>
<tr>
<td>Denosumab</td>
<td>60mg subcutaneous injection every 6 months</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>20mcg daily by subcutaneous injection</td>
</tr>
<tr>
<td></td>
<td>(max. duration 18 months, not to be repeated)</td>
</tr>
</tbody>
</table>

Calculate 10 yr probability of fracture Using FRAX tool
http://www.shef.ac.uk/FRAX/

Lifestyle Advice
- Adequate nutrition with calcium and Vitamin D
- Regular weight bearing exercise
- Avoid smoking and excess alcohol

DUXA & Recalculate FRAX

High risk

Intermediate

Low risk

Review Nov 2012

NHS Surrey Medicines Management Team  January 2011
Acknowledgments to North of the Tyne PCT for use of their Osteoporosis Treatment Guidelines.

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**Table Summarising NHS Surrey treatment options for osteoporosis**

<table>
<thead>
<tr>
<th>Drugs affecting bone metabolism</th>
<th>Indication / dose</th>
<th>Contra-indications</th>
<th>Side-effects</th>
<th>Counselling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronic acid tablets 10mg</td>
<td>Treatment of postmenopausal osteoporosis 10mg daily or 70mg once weekly.</td>
<td>Abnormalities of oesophagus, factors which delay gastric emptying hypocalcaemia.</td>
<td>Abdominal pain, dyspepsia, constipation, diarrhea, flatulence, oesophageal ulcer, melaena, dysphagia, abdominal distension, acid regurgitation, musculoskeletal pain, headache</td>
<td>Take on an empty stomach at least 30 minutes before breakfast or other medicines. Swallow whole with plenty of water while sitting or standing and remain upright for at least 30min after taking.</td>
</tr>
<tr>
<td>Alendronic acid 70mg once weekly</td>
<td>Treatment of osteoporosis in men 10mg daily. Prevention and treatment of corticosteroid-induced osteoporosis in postmenopausal women not receiving hormone replacement therapy 10mg daily.</td>
<td>Avoid if eGFR less than 35ml/minute/1.73m²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risedronate sodium 5mg tablets</td>
<td>Treatment of postmenopausal osteoporosis to reduce risk of vertebral or hip fractures 5mg daily or 35mg weekly. Prevention of osteoporosis (including corticosteroid induced osteoporosis) in postmenopausal women 5mg daily.</td>
<td>As for alendronic acid</td>
<td>Constipation, dyspepsia, nausea, abdominal pain, diarrhoea, headache, musculoskeletal pain</td>
<td>Swallow whole with full glass of water on rising. Take on an empty stomach at least 30mins before first food or drink of the day. Stand or sit upright for at least 30mins. Do not tablets at bedtime or before rising.</td>
</tr>
<tr>
<td>Risedronate sodium 35mg once weekly tablets</td>
<td></td>
<td>Avoid if eGFR less than 30ml/minute/1.73m²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strontium ranelate 2g / sachet</td>
<td>Treatment of postmenopausal osteoporosis to reduce risk of vertebral and hip fractures.</td>
<td>Caution – history of venous thromboembolism, phenyketonuria</td>
<td>Nausea, diarrhoea, venous thromboembolism headache, disturbances in consciousness, memory loss dermatitis, eczema</td>
<td>Take 2g in water at bedtime, avoid food for 2 hours before and after taking granules, particularly calcium-containing products. Avoid antacids for 2hrs after granules.</td>
</tr>
</tbody>
</table>

**MHRA / CHM advice Bisphosphonates: Osteonecrosis of the Jaw (Oct 2007 and Nov 2009)**

Patients who are prescribed bisphosphonates should have a dental examination, prior to treatment, if they have poor dental health. During bisphosphonate treatment patients should maintain good oral hygiene, receive routine dental check ups, and report any oral symptoms.

**Strontium ranelate: Severe allergic reactions**

Cases of severe hypersensitivity syndromes, including, in particular, drug rash with eosinophilia and systemic symptoms (DRESS), sometimes fatal, have been reported with the use of strontium ranelate. The DRESS syndrome is characterised by rash, fever, eosinophilia and systemic involvement (e.g. adenopathy, hepatitis, interstitial nephropathy, interstitial lung disease). Time to onset was usually around 3-6 weeks and the outcome in most cases favourable upon discontinuation of strontium ranelate and after initiation of corticosteroid therapy. Recovery could be slow and recurrences of the syndrome have been reported in some cases after discontinuation of corticosteroid therapy. Patients should be informed to stop strontium ranelate immediately and permanently when a rash occurs and to seek medical advice. Patients who have stopped treatment due to hypersensitivity reactions or other serious allergic reactions should not re-start therapy with strontium ranelate.

**Adherence with bone protection treatments**

The key factors that affect adherence to treatment are adverse events, lack of understanding of the condition/disease being treated, lack of information about the treatment (including potential side effects) and lack of follow up.

NHS Surrey suggests the following measures to help improve adherence with treatment:

- Ensure patients understand what is being treated (fracture risk/osteoporosis)
- Give patient detailed information about the treatment (how it works, potential side effects)
- Follow up the patient – a telephone follow up 3 to 6 months after starting treatment
- Encourage patients to contact Practice if any side effects / problems

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2 For further detailed information please refer to BNF(latest edition) and www.emcmedicines.org.uk