WIRRAL GUIDELINES FOR THE MANAGEMENT OF OSTEOPOROSIS

The scope of these guidelines covers:-
- Secondary prevention of osteoporotic fragility fractures
- Primary prevention of osteoporosis
- Prevention and treatment of glucocorticoid induced osteoporosis

Key to guidelines

<table>
<thead>
<tr>
<th>History of previous fragility fracture</th>
<th>See guideline for secondary prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>No previous fragility or low trauma fracture</td>
<td>See guidelines for primary prevention</td>
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<tr>
<td>On oral corticosteroids or high dose inhaled corticosteroids &gt; 3 months</td>
<td>See guideline for corticosteroid induced osteoporosis</td>
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</tbody>
</table>

Lifestyle Advice
- Balanced diet including adequate calcium and vitamin D
- Regular Weight-bearing exercise eg. Walking, Dancing, Skipping, Gym
- Stop Smoking
- Reduce Alcohol intake

Calcium and vitamin D
Calcium and vitamin D supplements should be co-prescribed with all osteoporosis treatments unless there is evidence of an adequate dietary calcium intake. They should be prescribed routinely for frail elderly individuals who are housebound or care home patients. The recommended daily dose is calcium 1 to 1.2g and vitamin D3 800 units which can be obtained by prescribing one of the following according to patient preference.
- Adcal D3® or Adcal D3 Dissolve® (effervescent tablets) – 1 tablet twice daily
- Calceos® 1 tablet twice daily
- Calcichew D3 Forte® 1 tablet twice daily
- Natecal D3® 1 tablet twice daily
- Calfovit D3® 1 sachet once daily (granules to make liquid preparation)

Falls prevention
People at high risk of falls are at high risk of sustaining a fragility fracture
Consider:-
- Completing Basic Falls Risk Assessment Tool (Wirral FRAT)
- Referral to Falls Prevention Service
- Referral to Medicines Management Team for a Clinical Medication Review
SECONDARY PREVENTION
(History of previous fragility fracture)

Lifestyle advice for all, routine tests and further investigations if indicated (see table 1 and 2) and consider secondary causes (see table 3)

- Over 75 years
  - DEXA only if clinically appropriate

- Post menopausal women less than 75 years and men over 65 years
  - Refer for DEXA

- Osteoporosis (t < -2.5)
  - Osteopenia (t -1 to -2.5)
    - OR
    - Normal (t > -1)

TREAT
1st line: alendronate 70mg once weekly

If unable to tolerate alendronate
2nd line: risedronate 35mg once weekly
OR ibandronate 150mg once monthly if failure to comply with weekly dosing

If bisphosphonates contra-indicated or patient intolerant of bisphosphonates
3rd line: strontium ranelate one sachet (2g) at bedtime
OR raloxifene 60mg once daily (women only)

If intolerant or unsuitable for both bisphosphonates and strontium,
Specialist referral for consideration of other treatments e.g. zolendronic acid.
See table 4

N.B. calcium and vitamin D to be prescribed with above treatment options if appropriate; see page 1

Above treatment threshold

Assess risk of fracture using FRAX
www.shef.ac.uk/FRAX

Below treatment threshold

Lifestyle advice

Patients with osteopenia (t score -1 to -2.5) should be re-scanned in 3 years

Consider HRT only for women with menopausal symptoms and/or intolerant of other treatments

NB: only alendronate 10mg daily & risedronate 35mg weekly are licensed for use in men.
**PRIMARY PREVENTION OF OSTEOPOROSIS I**
(No previous fragility or low trauma fracture)

### Independent clinical risk factors for post menopausal women (RF)
- Parental history of hip fracture
- Regular alcohol intake >4 units/day
- Rheumatoid Arthritis
- Prolonged immobility

### Indicators of Low BMD for post menopausal women (ILB)
- Low BMI <22kg/m²
- Untreated premature menopause
- Medical conditions Crohn’s disease; Ankylosing Spondylitis
- Prolonged immobility

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**Lifestyle advice for all, routine tests and further investigations if indicated (see table 1 and 2) and consider secondary causes (see table 3)**

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**Post menopausal women**
- Over 75 years plus 2 or more RF or ILB
- DEXA only if clinically appropriate

**Post menopausal women**
- 70-75 years plus 1RF OR 1ILB
- 65-69 years plus 1RF
- Less than 65 yrs plus 1RF AND 1 ILB

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**TREAT**

**1st line:** alendronate 70mg once weekly

*If unable to tolerate alendronate*

**2nd line:** risedronate 35mg once weekly

*OR* ibandronate 150mg once monthly if failure to comply with weekly dosing

*If bisphosphonates contra-indicated or patient intolerant to bisphosphonates*

**3rd line:** strontium ranelate one sachet (2g) at bedtime

*If intolerant or unsuitable for both bisphosphonates and strontium, Specialist referral: for consideration of other treatments e.g. zolendronic acid. See table 4*

*N.B. calcium and vitamin D to be prescribed with above treatment options if appropriate; see page 1*

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**Refer for DEXA**

**Osteoporosis (t < -2.5)**

**Osteopenia (t -1 to -2.5)**

**Normal (t > -1)**

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**Lifestyle advice**

Patients with osteopenia (t score -1 to -2.5) should be rescanned in 3

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**Not meeting NICE criteria for assessment but concern for bone health?**

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**High risk**

**Assess risk of fracture using FRAX**

[www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)

**Low risk**

**Medium risk:** - DEXA if not already done & reassess risk factors

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NB. Only alendronate 10mg daily and risedronate 35mg weekly are licensed for use in men
PREVENTION AND TREATMENT OF GLUCOCORTICOID INDUCED OSTEOPOROSIS

Commitment or exposure to oral glucocorticoids for > 3 months or high dose inhaled corticosteroids for ≥ 3 months

Age < 65 years

Previous fragility fractures or incident fractures during glucocorticoid therapy

Age ≥ 65 years

No previous fragility fractures

Measure BMD via DEXA scan (hip and/or spine)

<table>
<thead>
<tr>
<th>t &gt; 0</th>
<th>t 0 to -1.5</th>
<th>t ≤ -1.5</th>
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<tr>
<td>Reassure General measures</td>
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<td>Consider treatment depending on age and fracture probability</td>
</tr>
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</table>

Repeat BMD not indicated unless very high dose of glucocorticoid required

Repeat BMD in 3 years if glucocorticoids continue

General measures and treatment

TREAT

1st line alendronate 70mg orally once a week

2nd line risedronate 35mg orally once a week

Plus calcium and vitamin D if appropriate

Continue for one year post steroid then consider reassessment

GENERAL MEASURES

- Reduce dose of glucocorticoid when possible
- Consider glucocorticoid sparing therapy eg azathioprine if appropriate
- Consider alternative route of glucocorticoid administration
- Recommend good nutrition, regular weight bearing exercise, maintain body weight
- Avoid tobacco use and excess alcohol
- Assess falls risk and give advice if appropriate

Consider cumulative effects of oral steroid courses and high dose inhaled steroids i.e. beclomethasone 800mcg, budesonide 800mcg or fluticasone 500mcg daily
### Table 1: Routine tests for all people with suspected osteoporosis
- U&Es & creatinine
- FBC
- ESR
- Bone profile
- LFTs
- Serum TSH

### Table 2: Further investigations if indicated
- Lateral thoracic and lumbar spine X rays
- Bence Jones protein
- Serum paraproteins
- Immunoglobulins
- Serum FSH (women with unclear hormonal status)
- Serum testosterone, LH, SHBG (in men)
- Isotope bone scan
- Serum 250HD and PTH

### Table 3 Secondary causes of osteoporosis
(Exclude secondary causes especially if previous fracture or Z score <-1.5)

#### Secondary causes of osteoporosis (may indicate need for DEXA)
- Untreated hypogonadism;
- Early or surgical menopause;
- Also disease associated with increased risk of osteoporosis eg
  - Chronic liver disease
  - Hyperparathyroidism
  - Hyperthyroidism
  - Malabsorption syndromes
  - Inflammatory bowel disease, coeliac disease
  - Rheumatoid arthritis
  - Type 1 diabetes
  - Organ transplantation
  - COPD
  - Chronic HIV and treatment of HIV

#### Risk factor for osteoporosis
- Radiological osteopenia

### Table 4 Specialist Referral
- Severe osteoporosis (multiple fractures and severe pain)
- Corticosteroid users already on prophylaxis who subsequently fracture
- Unexplained osteoporosis in patients less than 40 years
- Pre-menopausal women
- Males less than 65 years
- Other metabolic bone disease
- Malignancy
- Aromatase inhibitor treatment
- Treatment for prostate cancer
- Intolerant or non-compliant with standard treatments
Adherence and Osteoporosis Treatments
Adherence to specific dosing regimes is essential to ensure effectiveness of all osteoporosis therapy. Patients should be given detailed information about their treatment e.g. how it works, how to take it, why they have to take it long term and possible side effects. A review of adherence and tolerance after 3 months would be beneficial. Prior to considering a change of treatment check instructions for administration have been followed correctly. Community pharmacists are providing Medicine Usage Reviews (MURs) which focus on improving adherence to osteoporosis treatments. GPs can refer patients to this service. An unsatisfactory response to treatment occurs if a patient has another fragility fracture despite adhering fully to treatment for 1yr and there is also evidence of a decline in BMD below their pre-treatment baseline.

Background to guidelines

NICE guidelines
In October 2008, NICE produced two technology appraisal (TA) documents
• TA 160 Alendronate, etidronate, risedronate and strontium ranelate for the primary prevention of osteoporotic fragility fractures in post menopausal women.
• TA 161 Alendronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in post menopausal women.
These TAs do not include prevention and treatment in men with osteoporosis or individuals treated with glucocorticoids.

After consideration of NICE guidance the steering group decided not to include etidronate in its treatment recommendations due to its compliance and efficacy issues. Oral ibandronate has been included as it has been approved for use by the Wirral Drug and Therapeutics Committee (D&T). Intravenous zolendronic acid has also been approved by D&T for secondary prevention of osteoporosis for use in secondary care and so is included in these guidelines under specialist referral.

NOGG guidelines
This clinical guideline was also produced in October 2008. It incorporates a fracture risk assessment tool (FRAX) which assesses the 10 year probability of a fracture without necessarily measuring BMD. It considers a wider range of risk factors, some with different parameters to NICE guidance. The FRAX tool can be found on www.shef.ac.uk/Frax

These guidelines will cover the majority of patients but clinical judgement should be used at all times.
References

Abbreviations and Definitions
BMI = Body Mass Index
BMD = Bone Mineral Density
DEXA = Dual Energy X-Ray absorptiometry
FRAX = Fracture Risk Assessment Tool
NICE = National Institute for Health and Clinical Excellence
NOGG = National Osteoporosis Guidelines Group
Fragility Fracture = A fracture resulting from minimal trauma e.g. fall from standing height or less or no identifiable trauma

NICE definitions of intolerance to drug treatment
Alendronate or risedronate: persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment and that occurs even though the instructions for administration have been followed correctly.
Strontium ranelate: persistent nausea or diarrhoea either of which warrants discontinuation of treatment.

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