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>
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<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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Lifestyle Advice
- Balanced diet including adequate Calcium and Vitamin D.
- Stop Smoking – risk factor that is part dependent on bone mineral density (BMD).
- Regular Weight-bearing exercise should be advised e.g. walking, dancing, skipping, gym
- Reduce alcohol intake – relationship between alcohol risk and fracture risk is dose-dependent

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. A daily calcium intake of between 700 – 1200mg, ideally achieved through dietary intake, is advised. In postmenopausal women and older men (≥50 years) at increased risk of fracture, a daily dose of 800IU cholecalciferol should be advised - see Wirral Vitamin D Guidelines at: [http://mm.wirral.nhs.uk/guidelines/](http://mm.wirral.nhs.uk/guidelines/)

Please follow ScriptSwitch recommendations for cost effective choice in primary care.

MHRA recommends no changes to the prescribing of calcium and vitamin D supplements despite concerns about increased cardiovascular risk raised in a recent meta-analysis. [http://www.mhra.gov.uk/SafetyInformation/DrugSafetyUpdate/CON131932](http://www.mhra.gov.uk/SafetyInformation/DrugSafetyUpdate/CON131932)

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) [http://staff.wirralct.nhs.uk/images/3__FRAT-_--final_version_controlled_July_15.pdf](http://staff.wirralct.nhs.uk/images/3__FRAT-_--final_version_controlled_July_15.pdf)
- For information on rehabilitation visit: [http://www.wirralct.nhs.uk/rehabilitation](http://www.wirralct.nhs.uk/rehabilitation)
- Refer to Medicines Management and Optimisation Team for a 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
DEXA not usually indicated

People aged between 50-75 years old
(<50yrs specialist referral)

Refer for DEXA

Osteoporosis
(t < -2.5)

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

TREAT
1st line: Alendronic acid 70mg once weekly
For recommendation by rheumatologists only - If unable to swallow standard alendronic acid tablets use alendronic acid effervescent 70mg tablets once weekly

2nd line: Risedronate sodium 35mg once weekly
OR ibandronic acid 150mg once monthly if failure to comply with weekly dosing
If bisphosphonates contra-indicated or patient intolerant of bisphosphonates

3rd line:Raloxifene 60mg once daily (females only)
If intolerant or unsuitable for both bisphosphonates and Raloxifene

Specialist referral for consideration of other treatments e.g. Denosumab – please see MHRA advice at: https://www.gov.uk/drug-safety-update/denosumab-prolia-xgeva-reports-of-osteonecrosis-of-the-external-auditory-canal, Zoledronic acid or Teriparatide (high cost restricts its use to those at very high risk, particularly for vertebral fractures). See table 4

Calcium and vitamin D to be prescribed with above treatment options if appropriate (see page 1)

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

Above treatment threshold

Below treatment threshold

Consider HRT only for women with menopausal symptoms and/or intolerant of other treatments
PRIMARY PREVENTION
(No previous fragility or low trauma fracture)

<table>
<thead>
<tr>
<th>Independent clinical risk factors for post-menopausal women (RF)</th>
<th>Indicators of Low BMD for post-menopausal women (ILB)</th>
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<tbody>
<tr>
<td>Parental history of hip fracture</td>
<td>Low BMI &lt;22kg/m²</td>
</tr>
<tr>
<td>Regular alcohol intake &gt;4units / day</td>
<td>Untreated premature menopause</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>Medical conditions Crohn’s disease; Ankylosing Spondylitis</td>
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<tr>
<td>Prolonged immobility, height loss and kyphosis</td>
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</tbody>
</table>

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

Post menopausal women
Over 75 plus 2 or more RF or ILB
DEXA not usually indicated

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

TREAT
1st line: Alendronic acid 70mg once weekly
For recommendation by rheumatologists only – if unable to swallow standard alendronic acid tablets use alendronic acid effervescent 70mg tablets once weekly.

2nd line: Risedronate sodium 35mg once weekly
OR Ibandronic acid 150mg once monthly if failure to comply with weekly dosing

If bisphosphonates contra-indicated or patient intolerant to bisphosphonates:

Specialist referral: for consideration of other treatments e.g. Denosumab or Zoledronic acid. See table 4

Calcium and Vitamin D to be prescribed with above treatment options if appropriate (see page 1)

Refer for DEXA
Osteopenia (t -1 to -2.5) OR Normal (t > -1)

Osteoporosis (t < -2.5)

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

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

Low Risk

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

NB. Only alendronic acid 10mg daily, risedronate sodium 35mg weekly, zoledronic acid and denosumab are licensed for use in men.
PREVENTION AND TREATMENT OF GLUCOCORTICOID INDUCED OSTEOPOROSIS

Commitment or exposure to oral glucocorticoids (≥7.5 mg/day prednisolone) 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

See associated investigations and if indicated, further investigations see table 1 and 2)

No previous fragility fractures

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

General measures and treatment

TREAT

1st line Alendronic acid 70mg orally once a week for patients unable to swallow standard alendronic acid tablets consider alendronic acid effervescent 70mg tablets once weekly - recommendation by rheumatologists only.

2nd line – Risedronate sodium 35mg orally once a week

Plus – calcium and vitamin D if appropriate.

Continue for one year post steroid then consider reassessment.

*For patients intolerant to bisphosphonates seek specialist advice.

GENERAL MEASURES

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

Consider cumulative effect of oral steroid courses and high dose inhaled steroids.
### Table 1: Routine tests for all people with suspected osteoporosis
- U&Es & creatinine
- FBC
- ESR or CRP
- 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, (vitamin D) and PTH

### Table 3 Secondary causes of osteoporosis
(Exclude secondary causes especially if previous fracture or Z score <-1.5)
- Endocrine - hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy
- Gastrointestinal - coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption
- Rheumatological – rheumatoid arthritis; other inflammatory arthropathies
- Haematological - multiple myeloma; haemoglobinopathies; systemic mastocytosis
- Respiratory - cystic fibrosis; chronic obstructive pulmonary disease
- Metabolic – homocystinuria
- Chronic renal disease
- Immobility due, for example to neurological injury or disease
- Early or surgical menopause;
- Hyperparathyroidism
- Hyperthyroidism
- Hyperprolactinaemia
- Diabetes
- Cushing’s disease
- Organ transplantation
- Chronic HIV and treatment of HIV

### Risk factor for osteoporosis
- Radiological osteopenia
- Living in a care home
- Taking drugs that may impair bone metabolism (such as anti-convulsants, selective serotonin reuptake inhibitors, thiazolidinediones, proton pump inhibitors and antiretroviral drugs).

### Table 4 Specialist Referral
- Severe osteoporosis (multiple fractures and severe pain)
- Corticosteroid users already on prophylaxis who subsequently fracture
- Unexplained osteoporosis in patients <50 years
- Pre-menopausal women
- Other metabolic bone disease
- Malignancy
- Aromatase inhibitor treatment
- Treatment for prostate cancer
- Intolerant or non-compliant with standard treatment
Introduction
NOGG clinical guideline was updated in March 2017 and reviews the assessment and diagnosis of osteoporosis. 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 at [www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX). Some clinicians use QFracture rather than FRAX. These guidelines don’t use QFracture as it does not incorporate DEXA results, has no thresholds and no treatment levels.

Patient Counselling
- 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.

Information for Prescribers
- 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.
- Optimum duration of bisphosphonate has not yet been clarified. It is important to review long-term bisphosphonate therapy if they are still indicated regularly.

Monitoring
NOGG have produced an algorithm for long-term monitoring of bisphosphonates in postmenopausal women – please see below.

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**Bisphosphonates: algorithm for long-term treatment monitoring**

**No fracture**

- Recurrent fracture(s)
- Prevalent vertebral fracture(s)**

**FRAX + BMD after 3-5* years**

- Above NOGG intervention threshold or hip BMD T-score ≤-2.5
- Check adherence
- Exclude 2 causes
- Re-evaluate treatment choice
- Continue treatment

- Below NOGG intervention threshold and hip BMD T-score >-2.5
- Consider drug holiday
- Repeat FRAX + BMD in 1.5-3 yrs

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**3 yrs for zoledronic acid**

5 yrs for other BPs

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**In patients taking oral BPs consider continuation if:**
- age > 75 yrs
- previous hip fracture
- current oral GC therapy ≥ 7.5 mg/d prednisolone

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[BPs – bisphosphonates, GC’s – glucocorticoids]

Compston et al 2014
• 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.

• Community pharmacists can provide medicine use reviews (MURs) which can focus on improving adherence to osteoporosis treatments. GPs can refer patients to this service.

References
5. Osteoporosis Guideline Group (NOGG). March 2017

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