

## Guidelines for the Prevention and Treatment of Osteoporosis

This guideline partially replaces NICE TA160 and TA161 and incorporates TA464.

### Primary care options:

Indication	Drug	Formulation	Dose
Primary and secondary prevention of osteoporotic fragility fractures in postmenopausal women. <a href="#">MHRA Alert Risk of Bisphosphonate Treatment</a>	Alendronic acid	70mg tablet	70mg once a week
	Risedronate sodium	35mg tablet	35mg once a week
	Ibandronic acid	150mg tablet	150mg once a month
Prevention and treatment of corticosteroid induced osteoporosis. (In all men and women aged > 65 years who take corticosteroids of any dose for more than 3 months, including high dose inhaled corticosteroids or patients on 3/4 courses of prednisolone in a year.)	Alendronic acid	10mg tablet	10mg once a day
	Risedronate sodium	5mg tablet	5mg once a day
Treatment of osteoporosis in men.	Alendronic acid	10mg tablet	10mg once a day
	<b>Weekly Alendronic acid is not licensed for the treatment of osteoporosis in men</b>		
	Risedronate sodium	35mg tablet	35mg once a week

### Secondary care options:

Indication	Drug	Formulation	Dose
Treatment of postmenopausal osteoporosis with at least a 10% fracture risk	Ibandronic acid	3mg/ml IV injection	3mg/ml once 3 monthly
	Zoledronic acid	IV infusion	5mg over at least 15 minutes ONCE a year
Treatment of postmenopausal osteoporosis in women and in men at increased risk of fractures.	Denosumab	SC injection	60mg every 6 months. First dose to be administered in secondary care then passed to primary care under shared care agreement.
Treatment of postmenopausal osteoporosis in women and in men at increased risk of fractures. Treatment of corticosteroid induced osteoporosis	Teriparatide	SC injection	20mcg daily for maximum duration of treatment 24 months. Course not to be repeated. <b>Secondary care prescribing only</b>

### Calcium Supplements:

Indication	Drug and Formulation	Dose
Calcium and Vitamin D supplementation should be considered unless clinician is confident that patient has an adequate calcium intake and is vitamin D replete. <i>Calcium and Ergocalciferol BP preparations (Ca<sup>2+</sup> 97mg) have no clinical value in prevention or management of osteoporosis.</i>	Adcal D3 Chewable Tabs (Ca <sup>2+</sup> 600mg Colecalciferol 400iu)	One twice daily
	Adcal D3 Dissolve Eff Tabs (Ca <sup>2+</sup> 600mg Colecalciferol 400iu)	One twice daily
	Adcal D3 Caplets (Ca <sup>2+</sup> 300mg Colecalciferol 200iu)	Two twice daily
	Calcichew D3 Forte Chewable Tabs (Ca <sup>2+</sup> 500mg Colecalciferol 400iu)	One twice daily
	Calceos Chewable Tabs (Ca <sup>2+</sup> 500mg Colecalciferol 400iu)	One twice daily

### Targeting risk assessment:

Assessment of fracture risk should be considered in:

- Women aged 65 years and above
- Men aged 75 years and above

Assessment of fracture risk in women under 65 years and men under 75 years in the presence of risk factors such as:

- Previous fragility fracture
- Family history of hip fracture
- History of falls
- Currently taken or frequently taken oral or systemic glucocorticoids (>7.5mg prednisolone or equivalent for ≥3months)
- Low BMI (<18.5 kg/m<sup>2</sup>)
- Smoker
- Alcohol intake above recommended limits
- Other causes of secondary osteoporosis as outlines in table 1

**Table 1: Causes of secondary osteoporosis**

<b>Endocrine</b>	Hypogonadism including untreated premature menopause, treatment with aromatase inhibitors or androgen deprivation therapy, hyperthyroidism, hyperparathyroidism, hyperprolactinaemia, Crushing's disease, diabetes.
<b>Gastrointestinal</b>	Coeliac disease, inflammatory bowel disease, chronic liver disease, chronic pancreatitis, other causes of malabsorption.
<b>Rheumatological</b>	Rheumatoid arthritis, other inflammatory arthropathies.
<b>Haematological</b>	Multiple myeloma, haemoglobinopathies, systemic mastocytosis.
<b>Respiratory</b>	Cystic fibrosis, COPD.
<b>Metabolic</b>	Homocystinuria.
<b>Other</b>	Chronic renal disease, immobility.

Do **NOT** routinely assess fracture risk in people less than 50 years unless they have major risk factors.  
 Measure BMD (Bone Mineral Density) to assess fracture risk in people less than 40 years who have a major risk factor

### Methods of risk assessment

- Estimate absolute risk when assessing risk of fracture (e.g. predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage).
- Use either **FRAX** (without a BMD value if a DXA scan has not previously been undertaken) or **QFracture**, within their allowed age ranges. Above the upper age limits defined by the tools, consider people to be high risk.
- FRAX can be used for people age between 40 & 90 years, either with or without BMD values, as specified.
- QFracture can be for people age between 30 & 84 years. BMD values cannot be included in the risk algorithm.
- Interpret the estimated absolute risk of fracture in people aged above 80 years with caution, because predicted 10-year fracture risk may underestimate their short-term fracture risk.
- Take into account that risk assessment tools may underestimate fracture risk in certain circumstances, for example if a person:
  - Has a history of multiple fractures.
  - Has had a previous vertebral fracture(s),
  - Is taking high-dose systemic glucocorticoids,
  - Has a high alcohol intake.
  - Has other causes of secondary osteoporosis.
- Take into account that fracture risk can be affected by factors that may not be included in the risk tool e.g. living in a care home or taking drugs that may impair bone metabolism (e.g. anti-convulsants, SSRIs, thiazolidinediones, PPIs and anti-retrovirals).
- Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD with DXA in people whose fracture risk is in the region of an intervention threshold for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.
- Do **NOT** routinely measure BMD with DXA before starting treatments that may have a rapid adverse effect on bone density e.g. sex hormone deprivation treatment for breast or prostate cancer.
- Consider recalculating fracture risk in the future:
  - If the original calculated risk was in the region of the intervention threshold for a proposed treatment and only after a minimum of 2 years **OR**
  - When there has been a change in the person's risk factor

### Preventing fragility fractures:

- **Oral** bisphosphonates (Alendronic acid, Ibandronic acid and Risedronate sodium) are recommended as options for treating osteoporosis in adults only if the:
  - Person is eligible for risk assessment, **AND**
  - 10-year probability of osteoporotic fragility fracture is at least 1%.
- **Intravenous** bisphosphonates (Ibandronic acid and Zoledronic acid) are recommended as options for treating osteoporosis in adults if the:
  - Person is eligible for risk assessment, **AND**
  - 10-year probability of osteoporotic fragility fracture is at least 10%, **OR**
  - 10-year probability of osteoporotic fragility fracture is at least 1% and the person has difficulty taking oral bisphosphonates or these drugs are contraindicated or not tolerated.
- Estimate the 10-year probability of fragility fracture using the FRAX or QFracture risk tool.
- Choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient and/or carers, about the advantages and disadvantages of treatment available. These recommendations are not intended to affect current treatment with bisphosphonates started in the NHS prior to this guidance being published.

## Other considerations

	Risk Factors	Treatment	Comments
<b>Frail elderly</b>	Increased risk of falling, housebound or in residential home.	Calcium & Vitamin D supplements as above.	
<b>Proton pump inhibitors</b>	The risk of fractures increases by 10-40% above baseline mainly in the elderly, especially if PPIs are at high doses and long term (>1 year).	People taking long term PPIs should be treated on the lowest dose necessary to control symptoms. Patients should be reviewed periodically to assess symptom resolution and treatment tolerability and stop if no longer required.	
<b>Treatment options as above</b>	<p><b>Falls Prevention</b></p> <p>Review drug therapy. Home safety assessment and modification of environmental hazards. Use of mobility aids. Vision test/visual intervention, hearing test and footwear changes. Gait training and advice on the use of assistive devices. Treatment of cardiovascular disorders and postural hypotension. Social care support.</p>	<p><b>Lifestyle advice</b></p> <p>Adequate nutrition, especially Ca<sup>2+</sup> and vitamin D. Regular weight bearing exercise and balance training. Avoid tobacco and excessive alcohol.</p>	<p><b>Risk assessment for falls</b> (score 1 for each yes answer) History of fall in the previous year. Patient on four or more medications daily. Stroke or Parkinson's disease. Problems with balance. Is patient unable to rise from a chair unaided? (A score of 2 is medium risk, 3+ is high risk of falls)</p>

## Duration of treatment

Concerns over rare adverse effects of long-term bisphosphonate therapy, particularly osteonecrosis of the jaw and atypical femoral fractures, have raised questions about the optimal duration of therapy: [Bisphosphonates MHRA Alert](#)

Bisphosphonates are retained in bone for varying periods of time; beneficial effects may persist for some time after cessation of treatment. This has led to the suggestion that some patients may benefit from a period off treatment, in which treatment is stopped after some years and the need for continued therapy is subsequently reassessed:

- **People taking oral corticosteroids:** continue treatment with bisphosphonates and/or calcium and vitamin D until treatment with oral corticosteroids has stopped, then reassess the osteoporotic fragility fracture risk to determine the need for continuing treatment with a bisphosphonate and calcium and vitamin D
- **All other people:** The National Osteoporosis Guidelines Group recommends evaluating the continued need for **Zoledronic acid after 3 years, Alendronate, Ibandronate, or Risedronate after 5 years:**
  - **People who remain at high risk of an osteoporotic fragility fracture:** continue treatment with Alendronic acid for up to 10 years, and risedronate for up to 7 years. This includes people with any of the following risk factors:
    - Age over 75 years
    - A previous hip or vertebral fracture
  - **People with moderate or low risk:** Arrange a DXA scan and consider:
    - Continuing treatment if the T-score is less than -2.5. Reassess their fracture risk and bone mineral density (BMD) every 3-5 years.
    - Stopping treatment if the BMD T-score is greater than -2.5. Reassess their fracture risk and re-measure BMD after 2 years.

## References

BNF 74, September 2014. Accessed via: <https://bnf.nice.org.uk/>

Nice TA464: Bisphosphonates for treating osteoporosis 09 August 2011: <https://www.nice.org.uk/guidance/ta464>