

Give lifestyle advice to all patients:

Stop smoking, limit alcohol to recommended amount, increase levels of weightbearing exercise and have a diet good for general health

1. Postmenopausal Women

Recommendations (exclude secondary causes of fragility fracture, e.g. metabolic bone disease)

- Consult DXA guidelines (*Referral for DXA Scan at Ipswich Hospital: A guideline for clinicians*) for recommendations on who to refer for DXA scanning.
- Exclude secondary osteoporosis – See section 3.

CALCIUM and VITAMIN D

+

Bisphosphonates¹ are recommended as treatment for secondary prevention of osteoporotic fragility fractures:

- Women ≥ 75y without need for DXA
- Women 65-74y when osteoporosis is confirmed by DXA
- Women <65y if they have very low BMD [T≤-3SD] in DXA, or have confirmed osteoporosis plus one, or more, additional risk factor:
 - ▶ Low BMI (<19 kg/m²)
 - ▶ Family history of maternal hip fracture before 75y
 - ▶ Untreated premature menopause
 - ▶ Medical disorders independently associated with bone loss (i.e. chronic inflammatory bowel disease, RA, hyperthyroidism or coeliac disease)
 - ▶ Conditions associated with prolonged immobility.



Use any of the following as an alternative to bisphosphonates in women for whom bisphosphonates are contraindicated or who are physically unable to comply with the special recommendations for use of bisphosphonates, or who have had an unsatisfactory response to bisphosphonates, or who are intolerant of bisphosphonates.

STRONTIUM^{2a-c} is recommended as an alternative treatment option in postmenopausal women.

RALOXIFENE¹ is recommended as an alternative treatment option in postmenopausal women

CALCITONIN^{3, 4} is recommended as an alternative treatment option in postmenopausal women

HRT⁵ For the prevention of osteoporosis in women over 50 years of age, and with an increased risk of fracture, the balance of risks and benefits of HRT is such that it should no longer be the first choice of treatment. While HRT remains a treatment option for those who cannot use other therapies or for whom other therapies have been shown to be ineffective, such a treatment decision should be made with care.

TERIPARATIDE¹ is a treatment option for the women aged 65 years and older who have had an unsatisfactory response to bisphosphonates or intolerance to bisphosphonates, and:

- who have an extremely low BMD (with a T-score of approximately – 4 SD or below), or
- who have a very low BMD (with a T-score of approximately –3 SD or below) + multiple fractures (>2) + one, or more, additional age-independent risk factor: low body mass index (< 19 kg/m²); family history of maternal hip fracture before the age of 75 years; untreated premature menopause; conditions associated with prolonged immobility.

CALCIUM + VITAMIN D
Ca²⁺ 1000mg/day & Vitamin D 800 iu/day

+

ALENDRONATE

70mg/week (alternatively 10mg/day)

OR

RISEDRONATE

35mg/week (alternatively 5mg/day)

ETIDRONATE

Patients should be transferred to one of the above drugs, which have a better evidence profile, unless they wish to continue with Etidronate



STRONTIUM RANELATE

2g/day

RALOXIFENE

60mg/day

CALCITONIN

Intranasal, 200 units (1 spray)/day

HRT

(preparations and doses depend on the requirements for the treatment of menopause)

TERIPARATIDE

20µg/day (subcutaneous) – treatment limited to 18 months

HOSPITAL INITIATED ONLY

Evidence Level

Vertebral

Hip

1BMD

28-days cost⁸

[A] [A] [A]

[A] [A] [A]

[A] [C] [A]

[A] [B] [A]

[A] [–] [A]

[A] [–] [A]

[A] [A] [A]

[A] [–] [A]

£4.03 -
£10.73
See overleaf

£22.80
or £ 23.12

£ 20.30 or
£19.10

£12.57

£25.60

£19.86

£41.98

Dependent
on
preparation
and dose

£271.88

[A] At least one systematic review of RCTs, meta-analysis or RCTs with a very low risk of bias.
[B] A body of evidence from high quality of case control or cohort studies with a very low risk of bias. High probability relationship is causal.
[C] A body of evidence from well conducted case control or cohort studies with a low risk of bias and a moderate probability relationship is causal.
[–] No evidence of treatment effect at the time of producing the guidelines.

2. Glucocorticoid-induced osteoporosis in men and women^{6a,b}

When considering therapy with oral glucocorticoids with commitment or exposure for ≥3 months:

- Patients with a previous fragility fracture should have investigations to exclude other causes of osteoporosis.
- Patients aged <65 with previous fragility fracture or ≥65 should be started on treatment.
- Patients <65 should have their BMD measured by DXA scan (**start bisphosphonate treatment while waiting for DXA scan in vulnerable people**):
 - ▶ If the T score is ≤ -1.5 start treatment
 - ▶ If T score is between 0 and -1.5 repeat BMD in 1-3 years if glucocorticoids continued
 - ▶ If the T score is > 0 repeat BMD is not indicated unless very high doses of Glucocorticoids required.



All patients should receive advice on general measures



Calcium + Vitamin D



ALENDRONATE
or
RISEDRONATE

Both licensed for treatment in glucocorticoid-induced osteoporosis



If bisphosphonates not tolerated or contraindicated REFER to secondary care for advice

General measures:

- ▶ Reduce dose of glucocorticoid when possible
- ▶ Recommend good nutrition especially with adequate calcium and vitamin D
- ▶ Consider glucocorticoid-sparing therapy, e.g. azathioprine, if appropriate
- ▶ Consider alternative route of glucocorticoid administration
- ▶ Recommend regular weightbearing exercise
- ▶ Maintain body weight
- ▶ Avoid tobacco use and alcohol abuse
- ▶ Assess falls risk and give advice if appropriate

3. Men^{7a-d}

Management of osteoporosis in men is much less well researched than in women

- ▶ 30% of hip fractures occur in men
- ▶ morbidity and mortality resulting from osteoporotic hip fracture is higher in men than in women
- ▶ men are more likely than women to have a secondary cause for their osteoporosis



Exclude endocrine and metabolic and 2^o osteoporotic causes of fracture/osteoporosis:

- LH/testosterone (sample taken at 8-9am)
- Bone biochemistry (and PTH if Ca high or low)
- CRP/IgG (and serum/urine electrophoresis if high - ?myeloma)
- TFTs and LFTs, U&Es and creatinine

Refer to bone clinic (Dr Clunie / Dr Parkinson) if abnormalities/uncertainties



CALCIUM + VITAMIN D



ALENDRONATE

70mg/week (alternatively 10mg/day)

OR

RISEDRONATE

35mg/week (alternatively 5mg/day)

REFER all men for whom bisphosphonates are contraindicated, or who are physically unable to comply with the special recommendations for use of bisphosphonates, or who have had an unsatisfactory response to bisphosphonates, or who are intolerant of bisphosphonates

Alendronate: Increases BMD at hip and spine in men with osteoporosis. Reduces the risk of vertebral fracture and re-fracture in men with osteoporosis. Effect on non-vertebral fractures is inadequately researched. Is licensed for use in men with osteoporosis in the UK (in 10mg daily form).

Risedronate: Preliminary data suggests that Risedronate has a positive effect on BMD and vertebral fracture rates in men with osteoporosis. Is not licensed for use in men.

Calcium and vitamin D: Use of calcium and vitamin D improved BMD at femoral neck in men aged over 60 years. Fracture prevention studies are underpowered to determine if fracture rates are altered.

Strontium Ranelate: Inadequate data in men.

Teriparatide: Increases BMD in men with osteoporosis. Inadequate data on effect on fracture rates. Not licensed for use in men.

4. Premenopausal women

Refer premenopausal women with suspected fragility fracture to secondary care for further advice

Definitions

Osteoporosis: The WHO classifies osteoporosis as BMD T-score below -2.5 SD.

DXA: Dual-energy X-ray Absorptiometry

Fragility Fracture: fracture occurring on minimal trauma after age 40 years and includes forearm, spine, hip, ribs and pelvis.

Unsatisfactory response to bisphosphonates: occurs when a woman has a fragility fracture despite adhering fully to treatment for 1 year and there is also evidence of ≥5% decline in BMD below her pre-treatment baseline.

References

1. NICE Technology Appraisal 87. Jan 2005.
- 2a. SPHN. New Medicines Report – Strontium Ranelate. Dec 2004.
- 2b. London New Drugs Group. APC / DTC Briefing Document – Strontium Ranelate. Dec 2004.
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3. Scientific Advisory Council of the Osteoporosis Society of Canada. 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. CMAJ, 167; Nov 2002
4. Cranney et al. VI. Meta-Analysis of Calcitonin for the Treatment of Postmenopausal Osteoporosis. Endocrine Reviews 2002; 23(4):540-551
5. DoH Press Release 2003/0493. Further advice on the safety of HRT. 3 Dec 2003
- 6a. RCP. Glucocorticoid-induced osteoporosis: Guidelines for prevention and treatment. Dec 2004.
- 6b. PRODIGY Guidance – Osteoporosis – Treatment. Sept 2004
- 7a. Orwoll E. Treatment of Osteoporosis in men. Calcif Tissue Int. 2004; 75: 114-119
- 7b. Ringe et al. Risedronate reduces vertebral fractures in men with osteoporosis. J Bone Miner Res. 2003; 18: S160
- 7c. Kanis et al. Epidemiology of osteoporosis and fractures in men. Calcif Tissue Int. 2004; 75: 90-99
- 7d. Diamond et al. Guidelines for treatment of osteoporosis in men. Aust Fam Phys. 2001; 30: 787-791
8. MIMS. Apr 2005

Calcium & Vitamin D

Name (pack size)	Form	Calcium content per tab/sachet	Vit D content per tab/sachet	Dose	NHS cost per 28 days
Adcal D3 (100)	Chewable tablet	600mg	400IU	2 daily	£4.06
Cacit D3 (30)	Effervescent granules (sachet)	500mg	440IU	2 daily	£9.99
Calceos (60)	Chewable tablet	500mg	400IU	2 daily	£4.42
Calcichew D3 Forte (100)	Chewable tablet	500mg	400IU	2 daily	£4.20
Calfovit D3 (30)	Soluble powder (sachet)	1200mg	800IU	1 daily	£4.03
Calcichew D3 (100)	Chewable tablet	500mg	200IU	2 daily	£8.41

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Copies of these guidelines are available from
www.sphn.nhs.uk

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