

# Clinical audit: Osteoporosis prevention and treatment

Improving clinical practice for better patient health

## How am I managing patients at risk of osteoporotic fractures?

This clinical audit will assist you to assess fracture risk, manage modifiable risk factors, review use of anti-osteoporotic drug therapy, and assess medication adherence in adults at risk of osteoporotic fractures (i.e. those who have had a bone mineral density test, whether the result showed osteoporosis or not).

NPS has applied for clinical audit points in the 2005–07 triennium of the RACGP QA&CPD Program, total points for steps 1–5: 30 (Category 1), and the ACRRM PDP: 27 clinical audit points (including 20 mandatory points). Points are awarded only to participants who complete the review phase.

This audit is recognised for the Quality Prescribing Initiative of the Practice Incentives Program (May 2007 to April 2008).

## How does my management compare with best practice guidelines?

1. Use best practice guidelines

2. Review current practice

3. Implement change

5. Monitor progress

4. Review and reflect

### Assess overall fracture risk

Consider all risk factors in management decisions

In assessing fracture risk, consider age, gender, history of fragility fracture, family history, long-term systemic glucocorticoid use, bone mineral density (BMD), coexisting conditions, calcium and vitamin D intake, body mass index, physical activity level and falls history

### Manage modifiable risk factors

Ensure adequate calcium and vitamin D intake and address lifestyle issues

Use calcium and/or vitamin D supplements in appropriate doses where intake is inadequate  
Encourage lifestyle changes such as reducing excessive alcohol use, smoking cessation and appropriate physical activity

### Treat those at high risk

Use anti-osteoporotic drug therapy when indicated to prevent or treat osteoporosis

Use anti-osteoporotic drug therapy in patients with osteoporosis (BMD T-score  $\leq -2.5$ ) with or without a fracture history and those with osteopenia (BMD T-score from  $-1.0$  to  $-2.4$ ) and a fracture history

Use anti-osteoporotic drug therapy in patients using long-term high-dose systemic glucocorticoids with BMD T-score  $< -1.5$ , especially postmenopausal women and men over 65 years of age

### Address adherence to drug therapy

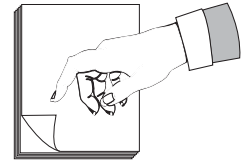
Improving medication adherence may reduce fracture rates

Assess each patient's medication adherence  
Use supportive strategies to improve and maintain medication adherence

# Notes on the clinical audit

Additional information to assist you to review your management.

Identify 20 patients prospectively as they present or retrospectively from a search of your medical records.



Patients should be aware that your practice participates in quality assurance activities; display the poster *Quality assurance in this practice and your privacy* and make available the patient information leaflet *Your health records and NPS clinical audits*.

Complete one double-sided audit form for each patient.

Include only patients with a known T-score from bone mineral density (BMD) testing. BMD T-score is required to apply some of the best practice standards of the audit.

If BMD T-score is known, include patients:

- with or without a history of fragility fracture (also called minimal- or low-trauma fracture), and/or
- using systemic glucocorticoids equivalent to  $\geq 7.5$  mg oral prednisone daily for  $> 3$  months.

Exclude patients:

- who do not have a known BMD T-score, or
- aged 18 years or under, or
- with Paget's disease.

## Assessment and management of risk factors for fractures/osteoporosis

### Assess overall risk of fracture/osteoporosis

Assess and manage the patient's risk factors for fracture. The presence of one or more major risk factors (see table) places the patient at high risk of fracture and increases the need for anti-osteoporotic drug therapy. Treat coexisting conditions such as hypogonadism to limit their effects and/or monitor the rate of bone loss closely.

Major risk factors for osteoporotic fractures <sup>1-5</sup>	Other significant risk factors for osteoporotic fractures <sup>1-5</sup>
<ul style="list-style-type: none"> <li>• advanced age (<math>&gt; 65</math> years)</li> <li>• low BMD</li> <li>• female gender</li> <li>• previous fragility fracture – the risk of new fractures increases exponentially with each successive fracture</li> <li>• family (especially parental) history of fragility fracture</li> <li>• long-term (<math>&gt; 3</math> months) systemic glucocorticoid use equivalent to <math>\geq 7.5</math> mg oral prednisone per day</li> <li>• low oestrogen exposure (e.g. menopause before 45 years of age, amenorrhoea for <math>&gt; 1</math> year)</li> <li>• low body mass index (<math>&lt; 20</math> kg/m<sup>2</sup>) or slim build</li> <li>• primary hypogonadism — both sexes</li> <li>• long term immobilisation</li> <li>• increased propensity for falls — more predictive of fracture in the elderly</li> </ul>	<ul style="list-style-type: none"> <li>• vitamin D deficiency</li> <li>• inadequate calcium intake</li> <li>• sedentary lifestyle (lying down, sitting)</li> <li>• current smoker</li> <li>• regular excessive alcohol use — evidence of an effect on fracture risk is conflicting. General health benefits are likely if alcohol use is kept below recommended levels (average intake <math>\leq 2</math> standard drinks/day for women and <math>\leq 4</math> standard drinks/day for men)</li> <li>• coexisting conditions that predispose patients to osteoporosis — anorexia nervosa, chronic liver or renal disease, hyperparathyroidism, hyperthyroidism, rheumatoid arthritis, malabsorption syndromes (e.g. Crohn's disease, coeliac disease, small bowel resection, inflammatory bowel disorders, cystic fibrosis).</li> </ul>

### Consider BMD, fracture history and overall fracture risk in treatment decisions

The decision to initiate anti-osteoporotic drug therapy (i.e. bisphosphonates, raloxifene, hormone replacement therapy, strontium, teriparatide, tibolone) depends on the patient's overall fracture risk, with a greater imperative to treat with advancing age, previous fragility fracture and lower BMD. General recommendations are given in the following table.<sup>1,4,6</sup>

Diagnosis	BMD T-score	Recommendation for anti-osteoporotic drug therapy
Osteoporosis	$\leq -2.5$	Treat, with or without history of fragility fracture
Osteopenia	$-1.0$ to $-2.4$	Treat, if history of fragility fracture
Normal bone density	$> -1.0$	Defer treatment

Patients with a BMD T-score of  $-3.0$  or less and aged 70 years or older, without a history of fragility fracture, may be eligible for subsidised bisphosphonate treatment under the Pharmaceutical Benefits Scheme (PBS; See insert, *Drug therapy used for prevention and treatment of osteoporosis*).

## Assess vitamin D status and prescribe a supplement if needed

Vitamin D deficiency reduces calcium absorption and increases the risk of osteoporosis, falls and fractures, especially in the elderly.<sup>7</sup>

### Groups most at risk of vitamin D deficiency<sup>7</sup>

- elderly and/or those in residential care — reduced vitamin D synthesis and absorption with ageing
- dark skinned people and/or those who wear clothing that covers most of the body and head
- patients with malabsorption syndromes (e.g. Crohn's disease, coeliac disease, small bowel resection, inflammatory bowel disorders, cystic fibrosis)
- patients who must avoid sunlight due to skin conditions such as cancer
- patients with chronic liver disease or using hepatic enzyme-inducing drugs e.g. rifampicin

The main source of vitamin D for Australians is exposure to sunlight, with only small amounts available in foods such as fatty fish (salmon, tuna, sardines and mackerel), egg yolk and vitamin D-fortified foods (margarine, some milk products).<sup>7</sup> Encourage elderly and other at-risk patients to include more of these food sources in their diet. Adults up to 50 years of age require a daily intake

of 5 micrograms, those aged 51 to 70 years need 10 micrograms and those over 70 years of age need 15 micrograms.<sup>8</sup>

Recommended periods of sun exposure (of face, hands and arms) for people with moderately fair skin, and where sun exposure is not blocked by sunscreen or glass are given in the table below.<sup>7</sup> People with highly pigmented skin need three to four times longer exposures.<sup>7</sup> The recommended exposure times produce around 25 micrograms (1000 IU) of vitamin D (cholecalciferol).<sup>7</sup>

Region	Recommended sun exposure times (minutes) at 10am or 2pm (11am or 3pm daylight-saving time) <sup>7</sup>	
	Summer	Winter
Cairns, Townsville	5–7	9–13
Brisbane	6–7	15–19
Perth	5–6	20–28
Sydney	6–8	26–28
Adelaide	5–7	25–38
Melbourne	6–8	32–52
Hobart	7–9	40–47

## Vitamin D supplements

Vitamin D in combination with calcium supplementation has been shown to reduce the risk of hip and other non-vertebral fractures in elderly people living in institutions or at home.<sup>7</sup> Prescribe a vitamin D supplement for patients at high risk of deficiency with little access to sunlight e.g. elderly in residential care, and for those diagnosed with vitamin D deficiency from serum 25-hydroxy-vitamin D (25-OHD) levels.<sup>1,4,7</sup> Routine measurement of serum 25-OHD levels is costly and is not recommended, but testing is appropriate when clinical signs of deficiency are present.<sup>9</sup>

### Recommended vitamin D supplement doses for various indications and patient groups<sup>3,7,10,11</sup>

Vitamin D indication	Patient group	Vitamin D supplement dose (cholecalciferol or ergocalciferol)
Prevention of vitamin D deficiency	Adult patients whose sun exposure is inadequate	≥ 10 micrograms (400 IU)/day, or ≥ 20–25 micrograms (800–1000 IU)/day if high risk of deficiency
Reduction of fracture risk	Elderly	Approx. 25 micrograms (1000 IU)/day
Treatment of mild vitamin D deficiency	25–50 nmol/L serum 25-hydroxy-vitamin D* (25-OHD)	Recommended dose is unclear; increase dietary intake and sun exposure where possible.
Treatment of moderate to severe vitamin D deficiency	< 25 nmol/L serum 25-OHD*	75–125 micrograms (3000–5000 IU)/day for at least 6–12 weeks, then 25 micrograms (1000 IU)/day once serum 25-OHD level returns to normal.

\* Reference levels may vary between laboratories.

### Cholecalciferol (vitamin D<sub>3</sub>)

- May be more effective than ergocalciferol in raising serum 25-OHD levels.<sup>10</sup>
- Available as a single ingredient in some vitamin D supplements (e.g. Blackmores Vitamin D<sub>3</sub>, Ostelin vitamin D, OsteVit-D). Combination with alendronate (Fosamax Plus) only provides 10 micrograms (400 IU) cholecalciferol, which is inadequate as sole treatment for vitamin D deficiency or to prevent vitamin D deficiency in those at high risk.<sup>10</sup>
- Avoid use of cholecalciferol or ergocalciferol in patients with severe renal impairment due to their inability to convert these precursors into the active form of vitamin D.<sup>10</sup>

### Ergocalciferol (vitamin D<sub>2</sub>)

- Available only in non-prescription vitamin supplements, but doses are often inadequate for treating or preventing vitamin D deficiency (check labels). Cholecalciferol or ergocalciferol can also be obtained from supplements containing cod liver oil or halibut liver oil, but these contain appreciable amounts of vitamin A, which can be toxic in excess.<sup>7</sup>

### Calcitriol

- Not appropriate for prevention or treatment of vitamin D deficiency in most cases.<sup>7</sup>
- High risk of hypercalcaemia and does not increase serum 25-OHD levels.<sup>7,10</sup>

## Assess dietary calcium intake and prescribe supplement if intake is inadequate

Assess dietary calcium intake in every patient and follow up patients whose intake has not been assessed. Prescribe a supplement if dietary intake is inadequate (see table opposite).<sup>4,8,10,11</sup>

Most of the trials showing efficacy of drugs used in fracture prevention and osteoporosis included calcium and vitamin D supplements. An adequate calcium intake is an essential part of drug therapy for reducing overall risk, along with other lifestyle interventions.<sup>4</sup> Doses over 600 mg per day should be divided due to limited absorption.<sup>11</sup>

Patient group	Recommended daily intake (diet and/or supplement) <sup>4,8</sup>
Pregnant women aged > 18 years	1 000 mg (≥ 3 serves calcium-rich food) e.g. 1 serve = 250 mL milk, or 200 g tub of yoghurt, or 40 g cheddar cheese
Women aged 19–50 years	
Men aged 19–70 years	
Women aged > 50 years	1 300 mg (≥ 4 serves calcium-rich food)
Men aged > 70 years	

## Manage modifiable risk factors

Lifestyle advice is part of first-line therapy in the prevention and treatment of osteoporosis. Manage all potentially modifiable risk factors to reduce the patient's overall fracture risk.

### Modifiable risk factors and potential strategies for management<sup>1,4,12–16</sup>

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• inadequate calcium intake — prescribe supplement if recommended dietary intake cannot be achieved</li> <li>• vitamin D deficiency — prescribe supplement</li> <li>• low body mass index (BMI &lt; 20 kg/m<sup>2</sup>) or slim build — if underweight, provide nutritional advice to increase calorie intake; refer to dietitian</li> <li>• smoking — smoking cessation advice, Quitline, pharmacotherapy</li> <li>• recurrent falls — strength and balance training, use of walking aids and/or hip protectors, correcting poor eyesight, checking for postural hypotension, reviewing use of medications causing sedation, hypotension or ataxia (e.g. benzodiazepines, tricyclic antidepressants, antihypertensive drugs), repair/removal of home hazards (e.g. slippery or uneven surfaces)</li> </ul> | <ul style="list-style-type: none"> <li>• regular excessive alcohol use — patient education, counselling, referral</li> <li>• inadequate physical activity — tailored exercise plan from physiotherapist, regular low intensity exercise for muscle strengthening, balance and stability (e.g. Tai Chi, hydrotherapy) for those with osteoporosis, weight-bearing and resistance exercises for others, post-fracture rehabilitation program</li> <li>• use of medications that may cause bone loss, especially long-term high dose glucocorticoids (others include phenytoin, carbamazepine, sodium valproate, excessive thyroid replacement, long-term heparin, chemotherapy, gonadotropin-releasing hormone agonists or antagonists, aluminium, proton pump inhibitors, selective serotonin reuptake inhibitors, rosiglitazone, pioglitazone) — review medication and monitor bone loss.</li> </ul> |
|---|--|

## Pharmacological management

### Use of anti-osteoporotic drug therapy

#### Bisphosphonates

- Reduce bone resorption, improve BMD and reduce fracture rates.<sup>11</sup>
- There is strong evidence for the benefits of alendronate (Fosamax, Alendro) and risedronate (Actonel) in fracture prevention trials, but less evidence for etidronate (Didronel).<sup>10,11</sup> The relative efficacy of bisphosphonates and other agents are unknown as there are no comparative fracture prevention trials.<sup>11,17</sup>
- **Duration of bisphosphonate therapy**
  - Optimal duration remains uncertain. The increase in BMD occurs mostly within the first two years of treatment. There is limited evidence of additional protective effects after 5 years of treatment. However, delayed or absent fracture healing has been reported with long-term treatment.<sup>10</sup> Stopping treatment results in increased remodelling, bone loss, progression of structural damage and increased fracture risk.<sup>4,6</sup>

- When deciding duration of treatment, take into account the patient's age, pre-existing fracture risk and BMD achieved with treatment.<sup>17</sup> If a significant increase in BMD occurs (e.g. > 5%) and patients are not at high risk of fractures, it may be reasonable to stop treatment after 3–5 years and monitor bone turnover markers and bone loss.<sup>4,6,10,11</sup>

#### Raloxifene (Evista)

- An alternative treatment for postmenopausal osteoporosis when bisphosphonates are not tolerated or contraindicated, or when there is a high risk of breast cancer (raloxifene reduces the risk of breast cancer).<sup>4,10</sup>
- Less useful in elderly women at higher risk of hip fracture as it does not prevent non-vertebral fractures.<sup>3,10</sup>
- Increased risk of venous thromboembolism — stop raloxifene if the patient is immobilised for any prolonged period.<sup>10</sup> Avoid during menopause as it can worsen menopausal symptoms.<sup>3</sup>

### Strontium (Protos)

- Increases bone formation, reduces bone resorption and decreases rate of vertebral and non-vertebral fractures.<sup>10</sup>
- Second-line option in postmenopausal osteoporosis when bisphosphonates are contraindicated or not tolerated.<sup>10,11,17</sup>
- Long-term safety data are needed on the consequences of skeletal uptake and possible muscular, thromboembolic and neurological adverse effects.<sup>10</sup>

### Hormone replacement therapy

- Benefits in fracture prevention may not outweigh the increased risk of breast cancer, stroke and cardiovascular disease.<sup>10,11</sup> Main role is in short-term (< 5 years) treatment of menopausal symptoms where fracture prevention is a secondary benefit.<sup>10,17</sup>
- Use only when other anti-osteoporotic drug therapy is contraindicated or not tolerated, and only after consideration of the benefit–harm profile for each individual.<sup>10</sup>

### Teriparatide (human parathyroid hormone; Forteo)

- Indicated for treatment of established postmenopausal osteoporosis and primary osteoporosis in men when other agents are considered unsuitable and fracture risk is high.<sup>10,11</sup>
- Use is restricted (due to incidence of osteosarcoma in animal studies) to those aged over 25 years, with no prior radiotherapy involving bone, and total lifetime exposure is limited to 18 months.<sup>11,18</sup>

### Androgens (e.g. testosterone, nandrolone)

- Indicated for men with hypogonadism to improve or maintain bone mass.<sup>4</sup>
- Should not be used alone for osteoporosis due to lack of documented efficacy in preventing fractures, risk of serious adverse effects and availability of other treatments with a better risk–benefit profile.<sup>10</sup>

## Improving adherence

Adherence with long-term medications for osteoporosis, including calcium and vitamin D supplements, is poor.<sup>17,23</sup> Common reasons for poor adherence include inconvenient or complex dosing regimens, adverse effects, lack of disease knowledge and the belief that the medication is not working.<sup>23,24</sup>

Improving adherence with osteoporosis therapy can improve BMD scores and lower the rate of fractures.<sup>25</sup>

### Calcitriol (active hormonal form of vitamin D)

- Modest clinical benefit and narrow therapeutic index in osteoporosis.<sup>10,19</sup>
- Reserve for those unwilling or unable to tolerate other drug therapy.<sup>10</sup> Monitor serum calcium closely for hypercalcaemia.<sup>10,11,19</sup>

### Specific patient groups

#### Postmenopausal women

- Alendronate and risedronate are recommended as initial therapy for treatment and prevention of osteoporosis. Second-line options are raloxifene (for vertebral fractures) and strontium.<sup>1,10,11</sup>

#### Men

- Alendronate or risedronate are recommended initial therapies for treatment and prevention of osteoporosis.<sup>1,10,11</sup>

#### Glucocorticoid-induced osteoporosis

- In glucocorticoid-induced osteoporosis patients have a higher fracture risk than those with postmenopausal osteoporosis at any given BMD.<sup>20</sup> To minimise risks, use the lowest effective dose of glucocorticoid for the shortest possible duration and use non-systemic formulations where appropriate.<sup>10,11,20</sup> Long-term, high-dose inhaled glucocorticoids may also increase the risk of osteoporosis, but to a lesser extent than systemic glucocorticoids.<sup>20</sup>
- Alendronate or risedronate are recommended as initial therapies for patients using long-term (> 3 months) systemic glucocorticoids ( $\geq 7.5$  mg oral prednisone/day or equivalent) when BMD is below  $-1.5$ , especially postmenopausal women and men aged over 65 years.<sup>4,20,21</sup>
- Calcium ( $\geq 1000$  mg/day) and vitamin D supplements are recommended as adjuncts in patients using long-term, high-dose glucocorticoids, and those using lower glucocorticoid doses or short-term therapy.<sup>4,11,20–22</sup>

Suggestions for improving adherence with long-term medication include:

- simplifying the drug regimen e.g. less frequent dosing
- use of memory aids and reminders
- involving carers or relatives where possible
- improving communication between doctor and patient about the purpose, likely duration and adverse effects of treatment and how to take the medication correctly
- involvement in self-management programs.<sup>1,26</sup>

## Confidentiality and privacy

You must sign and date the **Submission cover sheet** to participate in this audit.

By participating you agree to aggregation of your de-identified patient data and use of your personal data. Individual results of your clinical audit are kept confidential by NPS.

### What will happen to your patient data

- Your de-identified patient data forms are scanned and returned to you.
- Your individual results are provided to you only.
- Your data are aggregated with those of other participants and the de-identified aggregate results:
  - are provided to all participants
  - may be used in NPS evaluation and reports
  - are provided to the RACGP and ACRRM.

The RACGP has advised that program information may be shared with researchers and interested general practitioners for the purpose of continuing education coordination at the discretion of the QA&CPD Program.

### What will happen to your personal details

Your personal details:

- are provided to the mail house for processing
- are provided to the RACGP QA&CPD Program and/or ACRRM Professional Development Program for point allocation (if applicable)
- are recorded for the purpose of the PIP and NPS evaluation
- can be obtained from NPS by request in writing.

Individual clinical audit results will not be available after potentially identifying data are removed from NPS records at the close of the clinical audit cycle.

**Please note:** You are responsible for advising NPS of any changes of address during the audit cycle.

### Further information

#### Therapeutic enquiries

Holly Parsons — (02) 8217 8700

#### Audit and QPI enquiries

Kathleen Mulligan or Chun Fang Yu — (02) 8217 8700

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*The information contained in this material is derived from a critical analysis of a wide range of authoritative evidence. Any treatment decisions based on this information should be made in the context of the clinical circumstances of each patient.*



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# Drug therapy used for prevention and treatment of osteoporosis<sup>3,10,11,17,27</sup>

(See the *Clinical audit: Osteoporosis prevention and treatment guide* for citations)

Drug/class	Recommended doses	Indications	Evidence in fracture prevention	Contraindications	Drug and food interactions and management	Relevant PBS listing – see Schedule of Pharmaceutical Benefits for full listing <sup>27</sup>
<b>alendronate</b> Fosamax, Alendro, Alendro Once Weekly, Fosamax Once Weekly, Fosamax Plus – with cholecalciferol	10 mg daily or 70 mg weekly (oral)	Treatment and prevention of postmenopausal osteoporosis, treatment in men	Prevents vertebral, non-vertebral and hip fractures in osteoporosis, with or without fracture history	Oesophageal disorders (active oesophagitis, oesophageal ulceration, stricture, achalasia), inability to stand or sit upright for at least 30 minutes after drug administration, hypocalcaemia, (no studies in pregnancy or lactation)	<b>NSAIDs</b> — increased risk of oesophageal adverse effects: avoid combination or monitor carefully. <b>Antacids, calcium, iron, magnesium</b> — significantly reduce absorption: take at least 30 minutes after alendronate. <b>Food</b> — can decrease absorption to negligible levels: take alendronate in the morning with water at least 30 minutes before food.	Alendro Once Weekly, Fosamax Once Weekly or Fosamax Plus as the sole PBS-subsidised anti-resorptive agent for: <ul style="list-style-type: none"> <li>osteoporosis in patients aged ≥ 70 years and with BMD T-score –3.0 or less, or</li> <li>established osteoporosis in patients with fracture due to minimal trauma.</li> </ul>
	5 mg daily; 10 mg daily for postmenopausal women not using oestrogen (oral)	Treatment and prevention of corticosteroid-induced osteoporosis	May prevent vertebral fractures in osteopenia with fracture history			
<b>etidronate</b> Didronel, Didrocal – includes calcium	400 mg daily for 14 days, then 500 mg calcium daily for 76 days (oral)	Treatment of postmenopausal osteoporosis, prevention of corticosteroid-induced osteoporosis	Prevents vertebral fractures in osteoporosis with fracture history	Osteomalacia, osteolytic Paget's disease, hypocalcaemia, (no studies in pregnancy or lactation)	<b>Warfarin</b> — etidronate may increase INR: monitor INR. <b>Antacids, calcium, iron, magnesium</b> — significantly reduce absorption: do not take within two hours of etidronate. <b>Food</b> — significantly reduces absorption: etidronate can be taken at bedtime, separate from food by at least two hours.	<i>Didrocal</i> as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma.
<b>risedronate</b> Actonel, Actonel Once-a-Week, Actonel Combi – includes calcium	5 mg daily or 35 mg weekly (oral)	Treatment of osteoporosis, treatment and prevention of corticosteroid-induced osteoporosis	Prevents vertebral, non-vertebral and hip fractures in osteoporosis with fracture history Prevents vertebral fractures in osteoporosis without fracture history May prevent vertebral fractures in osteopenia with fracture history	Inability to stand or sit upright for at least 30 minutes after drug administration, hypocalcaemia, (no studies in pregnancy or lactation)	<b>NSAIDs</b> — increased risk of oesophageal adverse effects: avoid combination or monitor carefully. <b>Antacids, calcium, iron, magnesium</b> — significantly reduce absorption: take at least 30 minutes after risedronate. <b>Food</b> — can decrease absorption to negligible levels: take risedronate in the morning with water at least 30 minutes before food.	Actonel, Actonel Once-a-Week or Actonel Combi as the sole PBS-subsidised anti-resorptive agent for: <ul style="list-style-type: none"> <li>osteoporosis in patients aged ≥ 70 years and with BMD T-score –3.0 or less, or</li> <li>established osteoporosis in patients with fracture due to minimal trauma.</li> </ul> Repatriation PBS: Actonel or Actonel Once-a-Week for preservation of BMD in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment (for ≥ 3 months) with a dose ≥ 7.5 mg of prednisone or equivalent per day. (Patient must be osteopenic i.e. BMD T-score < –1.0).
<b>raloxifene</b> Evista (selective oestrogen receptor modulator)	60 mg daily (oral)	Prevention and treatment of postmenopausal osteoporosis	Prevents vertebral fractures in postmenopausal osteoporosis with or without fracture history May prevent vertebral fractures in osteopenia	Active or past history of venous thromboembolic events (including deep vein thrombosis, pulmonary embolism and retinal vein thrombosis), pregnancy, breastfeeding, premenopausal women, men	<b>Cholestyramine</b> — reduces absorption of raloxifene significantly: avoid combination or take raloxifene one hour before, or 4–6 hours after, cholestyramine and monitor clinical response. <b>Thyroxine</b> — raloxifene may interfere with absorption of thyroxine, reducing its efficacy: separate drug administration and monitor thyroid function. <b>Warfarin</b> — raloxifene may decrease anticoagulant effect: monitor INR and increase warfarin dose as needed.	Evista as the sole PBS-subsidised anti-resorptive agent for established postmenopausal osteoporosis in patients with fracture due to minimal trauma.
<b>hormone replacement therapy (HRT)</b> oestrogen ± progestogen (multiple brands)	Various	Prevention of postmenopausal osteoporosis in those with menopausal symptoms (limited role due to risks)	Prevents vertebral and non-vertebral fractures in postmenopausal women with or without fracture history (weaker evidence than other drug therapy)	History of thromboembolic disorder, unexplained uterine bleeding, severe liver disease, pregnancy, oestrogen-dependent tumour (e.g. breast cancer), cerebrovascular or coronary artery disease	<b>Insulin or oral antidiabetic drugs</b> — HRT can increase blood glucose levels and may alter control of diabetes or increase risk of hypoglycaemia. <b>Hepatic enzyme inducers</b> (e.g. phenytoin, carbamazepine, rifampicin, dexamethasone, St John's wort) — may increase oestrogen metabolism reducing its effects: when starting or stopping an enzyme-inducing agent, re-titrate oestrogen dose.	Various
<b>strontium</b> Protos	2 g daily (oral)	Treatment of postmenopausal osteoporosis	Prevents vertebral and non-vertebral fractures in postmenopausal osteoporosis with or without fracture history	Renal impairment – not recommended if creatinine clearance < 30 mL/min	<b>Calcium</b> — reduces absorption: give strontium at least two hours after calcium. <b>Tetracyclines</b> — may form poorly soluble chelates with strontium, reducing absorption and activity: give strontium at least two hours after tetracyclines. <b>Food</b> — take at bedtime, at least two hours after food, to avoid reduced absorption.	Protos as the sole PBS-subsidised anti-resorptive agent for established postmenopausal osteoporosis in patients with fracture due to minimal trauma.
<b>teriparatide</b> Forteo (active fragment of human parathyroid hormone)	20 micrograms daily (subcutaneously)	Treatment of postmenopausal osteoporosis and primary osteoporosis in men (when other agents unsuitable and high risk of fractures)	Prevents vertebral and non-vertebral fractures in established osteoporosis	Paget's disease of bone, hyperparathyroidism, prior radiotherapy of bone, under 25 years of age, lifetime duration limited to 18 months, (no studies in pregnancy or breastfeeding)	None known	Not listed
<b>calcium</b> Cal-Sup, Caltrate, Citracal, Sandocal	See <i>Guide</i> (page 4) for doses	Calcium deficiency, adjunctive treatment in osteoporosis	Calcium supplementation alone is unlikely to prevent fractures	Hypercalcaemia, hypercalciuria, digoxin toxicity, nephrolithiasis	<b>Bisphosphonates</b> (see above), <b>ciprofloxacin, norfloxacin, iron, tetracyclines, strontium</b> — calcium reduces absorption and/or activity: separate doses by at least 2 hours. <b>Polystyrene sulfonate resins</b> – concurrent calcium carbonate can lead to metabolic alkalosis: separate oral dosing by as much as possible and monitor closely, or use resin rectally. <b>Thyroxine</b> — calcium carbonate may reduce effect: allow 4–5 hours between drugs.	Repatriation PBS: Cal-Sup, Caltrate, Citracal — osteoporosis
<b>vitamin D + calcium</b> Bio Calcium, Caltrate with Vitamin D, Citracal+D, Ostelin Vitamin D and Calcium	See <i>Guide</i> (page 3,4) for doses	Calcium and vitamin D deficiency, adjunct for osteoporosis	May prevent hip and non-vertebral fractures in elderly institutionalised women with inadequate calcium and/or vitamin D intake	Hypercalcaemia, hypercalciuria, digoxin toxicity, nephrolithiasis	Other products containing vitamin D Interactions with calcium as above.	Not listed
<b>cholecalciferol</b> (vitamin D <sub>3</sub> )		Treatment and prevention of vitamin D deficiency, adjunct for osteoporosis	Vitamin D supplementation alone is unlikely to prevent fractures	Hypercalcaemia	Other products containing vitamin D	See cholecalciferol/alendronate (Fosamax Plus) listing above
<b>ergocalciferol</b> (vitamin D <sub>2</sub> )						Not listed
<b>calcitriol</b> Calcitriol-DP, Citrihexal, GenRx Calcitriol, Kosteo, Rocaltrol, Sical, Sitriol	0.25 micrograms twice daily (oral)	Treatment of osteoporosis, prevention of corticosteroid-induced osteoporosis	Limited evidence of prevention of vertebral fractures	Hypercalcaemia	<b>Digoxin</b> — increased risk of arrhythmias if hypercalcaemia is present: monitor plasma calcium concentration. <b>Thiazide diuretics, other drugs causing hypercalcaemia</b> (e.g. calcium supplements, lithium) — increase risk of hypercalcaemia: use with caution.	Calcitriol-DP, Citrihexal, GenRx Calcitriol, Kosteo, Rocaltrol, Sical — treatment for established osteoporosis in patients with fracture due to minimal trauma.

**Your patient code:** Do not use patient name. Use this to identify your patients for the Review Phase.

**Exclude patients with no known BMD T-score**

Use a **black biro** to mark a **cross (X)** in the box beside your response. If you make a mistake, use white correction fluid.



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## Assessment and management of risk factors for fractures/osteoporosis

### Non-modifiable risk factors

**1. Age (years):**

- 19–50     51–65     66–70     > 70

**2. Gender:**

- male     female ▼
- pre-menopausal
  - peri-menopausal
  - post-menopausal

**3. History of fragility fracture (minimal-trauma fracture)?**

- yes ▼     no     not known
- 1 fracture
  - ≥ 2 fractures

**4. Latest bone mineral density (BMD) T-score:**

(use lowest value if more than one site)

- ≤ -3.0 } — osteoporosis
- 2.9 to -2.5 } — osteoporosis
- 2.4 to -1.6 } — osteopenia
- 1.5 to -1.0 } — osteopenia
- > -1.0 } — normal

**Exclude patients with no known BMD T-score**

**5. Other risk factors present:** (see *Guide* – mark all that apply)

- family (especially parental) history of fragility fracture
- systemic glucocorticoid use for > 3 months (≥ 7.5 mg/day oral prednisone or equivalent)
- long-term immobilisation
- reduced oestrogen exposure (e.g. amenorrhoea, early menopause)
- condition that may cause osteoporosis (e.g. anorexia nervosa, hypogonadism)

to Q6 ↗

### Modifiable risk factors

**6. Risk factor(s) for vitamin D deficiency present:**

(see *Guide* – mark all that apply)

- none
- elderly and/or in residential care
- malabsorption syndrome (e.g. Crohn's disease)
- dark skin and/or head and body mostly covered with clothing
- sunlight avoided due to skin condition (e.g. cancer)
- not known

**7. Vitamin D deficiency present:** (see *Guide*)

- no deficiency (> 50 nmol/L serum 25-hydroxy-vitamin D [25-OHD])
- mild vitamin D deficiency (25–50 nmol/L serum 25-OHD)
- moderate–severe vitamin D deficiency (< 25 nmol/L serum 25-OHD)
- not known

**8. Dietary intake of calcium assessed?**

- yes ▼     no     not known

**Number of serves of calcium-rich foods per day:**

- ≤ 1 serve (0–350 mg)
- 2 serves (600–700 mg)
- 3 serves (approx. 1000 mg)
- ≥ 4 serves (approx. 1300 mg or more)
- not known

**9. Other risk factors present:** (see *Guide* – mark all that apply)

- low body mass index (< 20 kg/m<sup>2</sup>) or slim build
- sedentary lifestyle
- recurrent falls
- excessive alcohol use
- current smoker
- medications (other than systemic glucocorticoids) that may cause osteoporosis

to Q10 ↗

**10. Strategies to address modifiable risk factors**

	Already used	Planned
none	<input type="checkbox"/>	<input type="checkbox"/>
maintaining adequate calcium and vitamin D intake	<input type="checkbox"/>	<input type="checkbox"/>
regular exercise, improve inadequate nutrition	<input type="checkbox"/>	<input type="checkbox"/>
reducing falls risk (e.g. correct poor eyesight)	<input type="checkbox"/>	<input type="checkbox"/>
reduce alcohol use if excessive	<input type="checkbox"/>	<input type="checkbox"/>
smoking cessation	<input type="checkbox"/>	<input type="checkbox"/>
review medications (e.g. that may cause bone loss)	<input type="checkbox"/>	<input type="checkbox"/>
other (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>

**11. Coexisting conditions present:** (*drugs contraindicated* in these conditions are in brackets — mark all that apply)

- none of the listed conditions
- hypercalcaemia (*calcium, vitamin D*)
- hypercalciuria, digoxin toxicity, nephrolithiasis (*calcium*)
- hypocalcaemia, oesophageal disorder, unable to stay upright for 30 minutes (*oral bisphosphonates*)
- active/past history of venous thromboembolism (*raloxifene*)
- history of thromboembolic disorder, unexplained uterine bleeding, severe liver disease, oestrogen-dependent cancer, cerebrovascular or coronary heart disease (*hormone replacement therapy*)
- creatinine clearance < 30 mL/min (*strontium*)
- < 25 years of age, hyperparathyroidism, prior radiotherapy of bone, duration of teriparatide use > 18 months (*teriparatide*)

Record planned actions on *Action plan* to assist with Review Phase.

## Pharmacological management

<b>12. Is the patient currently using anti-osteoporotic drug therapy?</b> <input type="checkbox"/> yes ▼ mark all that apply <input type="checkbox"/> no ► go to Q15		<b>13. Dose</b> <input type="checkbox"/> 5 mg daily <input type="checkbox"/> 10 mg daily <input type="checkbox"/> 70 mg weekly <input type="checkbox"/> other _____ <input type="checkbox"/> 70 mg alendronate/70 mcg cholecalciferol weekly <input type="checkbox"/> other _____ <input type="checkbox"/> 200 mg daily <input type="checkbox"/> 400 mg daily <input type="checkbox"/> other _____ <input type="checkbox"/> 400 mg etidronate (14 days) and 500 mg calcium (76 days) <input type="checkbox"/> other _____ <input type="checkbox"/> 5 mg daily <input type="checkbox"/> 35 mg weekly <input type="checkbox"/> other _____ <input type="checkbox"/> 35 mg risedronate (once weekly) and 500 mg calcium (other 6 days) <input type="checkbox"/> other _____		<b>14. Concurrent therapy used — potential interactions (see Guide)</b> <input type="checkbox"/> antacid if taken within 2 hours of bisphosphonate <input type="checkbox"/> calcium, iron, magnesium or mineral supplements if taken within 2 hours of bisphosphonate <input type="checkbox"/> NSAID (alendronate, risedronate) <input type="checkbox"/> warfarin (etidronate)	
<b>If patient is taking bisphosphonate:</b> Has patient been educated on correct administration of oral bisphosphonate (i.e. remain upright for 30 minutes, take on an empty stomach)? <input type="checkbox"/> yes <input type="checkbox"/> no Duration of bisphosphonate therapy: <input type="checkbox"/> ≤ 5 years <input type="checkbox"/> > 5 years <input type="checkbox"/> not known					
<input type="checkbox"/> raloxifene (Evista)		<input type="checkbox"/> 60 mg daily <input type="checkbox"/> other _____		<input type="checkbox"/> cholestyramine <input type="checkbox"/> thyroxine <input type="checkbox"/> warfarin	
<input type="checkbox"/> hormone replacement therapy (oestrogen ± progestogen)				<input type="checkbox"/> antidiabetic drug <input type="checkbox"/> hepatic enzyme inducing drug (e.g. phenytoin)	
<input type="checkbox"/> strontium (Protos)		<input type="checkbox"/> 2 g daily <input type="checkbox"/> other _____		<input type="checkbox"/> calcium <input type="checkbox"/> tetracycline	
<input type="checkbox"/> teriparatide (Forteo)		<input type="checkbox"/> 20 mcg daily (subcutaneously) <input type="checkbox"/> other _____			
<input type="checkbox"/> other (e.g. tibolone, testosterone, pamidronate) _____					
<b>calcium:</b> <input type="checkbox"/> Cal-Sup <input type="checkbox"/> Caltrate <input type="checkbox"/> Citracal <input type="checkbox"/> Sandocal <input type="checkbox"/> other _____ <input type="checkbox"/> not known		<b>Number of tablets per day:</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> ≥ 3 <input type="checkbox"/> not known <small>(Elemental calcium per tablet: Cal-Sup, 500 mg; Caltrate, 600 mg; Citracal, 250 mg; Sandocal, 1000 mg)</small>		<input type="checkbox"/> bisphosphonate <input type="checkbox"/> ciprofloxacin, norfloxacin, iron, tetracycline <input type="checkbox"/> polystyrene sulfonate resins	
<b>calcium+cholecalciferol:</b> <input type="checkbox"/> Bio Calcium <input type="checkbox"/> Caltrate with Vitamin D <input type="checkbox"/> Citracal+D <input type="checkbox"/> Ostelin Vitamin D and Calcium <input type="checkbox"/> other _____ <input type="checkbox"/> not known		<b>Number of tablets/capsules per day:</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> ≥ 3 <input type="checkbox"/> not known <small>(Elemental calcium (mg)/cholecalciferol (mcg) per tablet or capsule: Caltrate with Vitamin D, 600/5; Ostelin Vitamin D and Calcium, 600/12.5; Citracal+D, 250/5; Bio Calcium, 360/2.5)</small>		<input type="checkbox"/> strontium <input type="checkbox"/> thyroxine <input type="checkbox"/> other product containing vitamin D	
<b>cholecalciferol:</b> <input type="checkbox"/> Blackmores Vitamin D <sub>3</sub> , OsteVit-D (25 mcg per tablet/capsule) <input type="checkbox"/> other _____ <input type="checkbox"/> not known		<b>Daily dose:</b> <input type="checkbox"/> 5 mcg (200 IU) <input type="checkbox"/> 10 mcg (400 IU) <input type="checkbox"/> 15 mcg (600 IU) <input type="checkbox"/> 25–50 mcg (1000–2000 IU) <input type="checkbox"/> 75–125 mcg (3000–5000 IU) <input type="checkbox"/> other _____ <input type="checkbox"/> not known		<input type="checkbox"/> other product containing vitamin D	
<input type="checkbox"/> ergocalciferol (multiple combination products)		<b>Daily dose:</b> <input type="checkbox"/> 5 mcg (200 IU) <input type="checkbox"/> 10 mcg (400 IU) <input type="checkbox"/> 15 mcg (600 IU) <input type="checkbox"/> other _____ <input type="checkbox"/> not known		<input type="checkbox"/> other product containing vitamin D	
<input type="checkbox"/> calcitriol (Calcitriol-DP, Citrihexal, Kosteo, Rocaltrol, Sical, Sitriol)		<b>Daily dose:</b> <input type="checkbox"/> 0.25 mcg <input type="checkbox"/> 0.50 mcg <input type="checkbox"/> 0.75 mcg <input type="checkbox"/> other _____ <input type="checkbox"/> not known		<input type="checkbox"/> digoxin <input type="checkbox"/> thiazide, other drug causing hypercalcaemia	

(mcg = micrograms)

### 15. Initial anti-osteoporotic drug therapy: (excluding calcium and vitamin D)

- |  |  |
|--|--|
| <input type="checkbox"/> never used drug therapy | <input type="checkbox"/> hormone replacement therapy |
| <input type="checkbox"/> same as current therapy | <input type="checkbox"/> strontium                   |
| <input type="checkbox"/> alendronate             | <input type="checkbox"/> teriparatide                |
| <input type="checkbox"/> etidronate              | <input type="checkbox"/> other _____                 |
| <input type="checkbox"/> risedronate             | <input type="checkbox"/> not known                   |
| <input type="checkbox"/> raloxifene              |  |

#### Reason for ceasing initial drug therapy:

- |   |   |
|---|---|
| <input type="checkbox"/> bisphosphonate therapy considered sufficient (e.g. good response after 5 years of treatment) | <input type="checkbox"/> contraindication                     |
| <input type="checkbox"/> patient suffered fracture  | <input type="checkbox"/> inadequate response                  |
| <input type="checkbox"/> switched to product with less frequent dosing  | <input type="checkbox"/> not tolerated (i.e. adverse effects) |
| <input type="checkbox"/> other (specify) _____  | <input type="checkbox"/> not known                            |

### 16. Have you assessed medication adherence (including calcium and vitamin D) by: (mark all that apply, where medication is being used)

- |  |   |
|--|---|
| <input type="checkbox"/> direct questioning e.g. How often would you forget to take your medicine? | <input type="checkbox"/> checking repeat prescription intervals |
| <input type="checkbox"/> other (specify) _____   | <input type="checkbox"/> not assessed                           |

### 17. Current strategies to improve or maintain medication adherence: (mark all that apply, where medication is being used)

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> none  | <input type="checkbox"/> patient education about treatment options and aims, adverse effects, expected duration | <input type="checkbox"/> enquire about and manage adverse effect(s)      |
| <input type="checkbox"/> use of memory aids and reminders e.g. Dosette | <input type="checkbox"/> provide Consumer Medicine Information (CMI)  | <input type="checkbox"/> patient referred to self-management program     |
| <input type="checkbox"/> involve carer/relative in administering drugs |   | <input type="checkbox"/> simplify drug regimen e.g. less frequent dosing |
| <input type="checkbox"/> other (specify) _____                         |   |  |

# Clinical audit: Osteoporosis prevention and treatment

Improving clinical practice for better patient health

## How am I managing patients at risk of osteoporotic fractures?

This clinical audit will assist you to assess fracture risk, manage modifiable risk factors, review use of anti-osteoporotic drug therapy, and assess medication adherence in adults at risk of osteoporotic fractures (i.e. those who have had a bone mineral density test, whether the result showed osteoporosis or not).

NPS has applied for clinical audit points in the 2005–07 triennium of the RACGP QA&CPD Program, total points for steps 1–5: 30 (Category 1), and the ACRRM PDP: 27 clinical audit points (including 20 mandatory points). Points are awarded only to participants who complete the review phase.

This audit is recognised for the Quality Prescribing Initiative of the Practice Incentives Program (May 2007 to April 2008).

## How does my management compare with best practice guidelines?

1. Use best practice guidelines

### Assess overall fracture risk

Consider all risk factors in management decisions

In assessing fracture risk, consider age, gender, history of fragility fracture, family history, long-term systemic glucocorticoid use, bone mineral density (BMD), coexisting conditions, calcium and vitamin D intake, body mass index, physical activity level and falls history

### Manage modifiable risk factors

Ensure adequate calcium and vitamin D intake and address lifestyle issues

Use calcium and/or vitamin D supplements in appropriate doses where intake is inadequate  
Encourage lifestyle changes such as reducing excessive alcohol use, smoking cessation and appropriate physical activity

### Treat those at high risk

Use anti-osteoporotic drug therapy when indicated to prevent or treat osteoporosis

Use anti-osteoporotic drug therapy in patients with osteoporosis (BMD T-score  $\leq -2.5$ ) with or without a fracture history and those with osteopenia (BMD T-score from  $-1.0$  to  $-2.4$ ) and a fracture history  
Use anti-osteoporotic drug therapy in patients using long-term high-dose systemic glucocorticoids with BMD T-score  $< -1.5$ , especially postmenopausal women and men over 65 years of age

### Address adherence to drug therapy

Improving medication adherence may reduce fracture rates

Assess each patient's medication adherence  
Use supportive strategies to improve and maintain medication adherence

2. Review current practice

3. Implement change

5. Monitor progress

4. Review and reflect





National Prescribing Service Limited



# Clinical audit enrolment form

## Osteoporosis prevention and treatment

This is the final NPS clinical audit offered in the RACGP 2005–2007 triennium.

### To enrol

Fill out the form below then return to NPS. Enrolments must be received at NPS by **Friday 28 September 2007**.

**Fax this form to:** 02 9283 2028  
**OR Telephone:** 02 8217 8700  
**OR Post to:** PO Box 1147,  
Strawberry Hills  
NSW 2012

Your free audit pack will be forwarded by mail.

### For more information

To see a sample audit form before enrolling, visit [www.nps.org.au/healthpro](http://www.nps.org.au/healthpro)

Holly Parsons { Phone: 02 8217 8700  
Kathleen Mulligan { Email: [info@nps.org.au](mailto:info@nps.org.au)

### Submission date

Completed clinical audit forms must be submitted to NPS by **Friday 26 October 2007**. Unfortunately, late submissions cannot be accepted.

### Participant details:

GP       GP registrar       Other medical specialist      (please mark relevant box)

Please use BLOCK LETTERS

Title       Dr       Mr       Mrs       Miss       Ms

Family name

Given name

Postal address

Town or Suburb

State or Territory       Postcode

Phone no. (  )       Prescriber no.

Fax no. (  )       Provider no.

NPS consults widely with general practitioners in the development of quality assurance activities.

Yes, I am interested in participating in the development of NPS quality assurance activities.

NPS adheres to the National Privacy Principles contained in the Privacy Act 1988 (Cwth). All personal information collected by NPS will be used only for mailing of NPS materials relating to this audit and/or evaluation purposes.

[See over for more details](#)

NPS is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.