NPS MEDICINEWISE PROFESSIONAL

PREVENTING FRACTURES IN OSTEOPOROSIS

TABLE 1

Criteria for PBS-subsidised treatment when initiating osteoporosis medicines[1]

Medicines	Criteria for PBS-subsidised treatment: Restriction applies ✓ Restriction does not apply ✗						
	corticosteroid-induced† osteoporosis in patients with BMD T-score ≤ −1.5	minimal trauma fracture‡	BMD T-score ≤ −2.5 in a patient ≥ 70 years	BMD T-score ≤ −3.0 in a patient ≥ 70 years	severe osteoporosis with high risk of fracture§	postmenopausal women	BMD T-score ≤ −3.0 with a new fracture.‖
alendronate* 70 mg oral; once weekly	✓	✓	✓	✗	✗	✗	✗
risedronate* 5/35/150 mg oral; once daily/once weekly/ once monthly	✓	✓	✓	✗	✗	✗	✗
zoledronic acid 5 mg intravenous infusion; once yearly	✓	✓	✗	✓	✗	✗	✗
denosumab 60 mg subcutaneous injection; once 6-monthly	✗	✓	✓	✗	✗	✗	✗
strontium ranelate 2 g sachet dissolved in 30 mL water, oral; once daily - PBS subsidy removed August 2016							
raloxifene 60 mg oral; once daily¶	✗	✓	✗	✗	✗	✓	✗
teriparatide 20 microgram subcutaneous injection; once daily¶**††	✗	✓	✗	✗	✓	✗	✓

Note: Some PBS-listed medicines carry restrictions regarding concomitant treatment with any other PBS-listed antiresorptive agent. Refer to the PBS for full list of restrictions.

* PBS-listed as a composite pack with colecalciferol alone and/or with calcium. † ≥ 7.5 mg prednisolone or equivalent daily; continuous treatment for ≥ 3 months. ‡ Fractures must be demonstrated radiologically and the year of X-ray or CT scan or MRI scan documented when treatment is initiated. § Patients must be contraindicated or intolerant to other osteoporosis medicines. ‖ Patient must have had 2 or more fractures due to minimal trauma and at least one new fracture after treatment with another osteoporosis medicine for 12 months. ¶ All checked restrictions must be satisfied for the subsidy to apply. ** Must be treated by a specialist or a consultant physician. †† Special restrictions apply for patients on continuing treatment who have been issued with an authority required prescription for this drug. Treatment must not exceed a lifetime maximum of 18 months.

-2.5
Osteoporosis: Exclude and manage causes of secondary osteoporosis

T-score
Osteopenia: Exclude and manage causes of secondary osteoporosis.

-1
Normal bone mass: Promote activities to reduce bone loss.

Consider laboratory tests to exclude secondary causes of osteoporosis that require management.[2,3]

TABLE 2

Indications for DXA scanning available on the MBS‡‡, [4]

Indication	MBS Item
For diagnosis	
Patients with a minimal trauma fracture to confirm a presumptive diagnosis of low BMD	12306
Patients aged ≥ 70 years	12323
To investigate bone loss in patients with one or more of the following: conditions associated with long-term corticosteroid use, conditions associated with excess glucocorticoid secretion, male hypogonadism, or female hypogonadism lasting more than 6 months before the age of 45	12312
To investigate bone loss in patients with one or more of the following conditions: primary hyperparathyroidism, chronic liver disease, chronic renal disease, proven malabsorptive disorders, rheumatoid arthritis or conditions associated with thyroxine excess	12315
For monitoring	
BMD proven by DXA at least 12 months previously	12306
BMD in patients with one or more of the following: conditions associated with long-term corticosteroid use, conditions associated with excess glucocorticoid secretion, male hypogonadism, or female hypogonadism lasting more than 6 months before the age of 45	12312
BMD in patients with one or more of the following conditions: primary hyperparathyroidism, chronic liver disease, chronic renal disease, proven malabsorptive disorders, rheumatoid arthritis or conditions associated with thyroxine excess	12315
BMD 12 months following a significant change in therapy for established low BMD or to confirm a presumptive diagnosis of low BMD following a minimal trauma fracture	12321

TABLE 3

Some comorbidities and medicines associated with an increase in bone loss or minimal trauma fractures§§,2,3,5,6

Comorbidities or conditions	Medicines
diabetes (type 1 or 2)	long-term antidepressants
inflammatory rheumatic diseases (rheumatoid arthritis, systemic lupus erythematosus, ankylosing spondylitis)	anti-epileptics, particularly hepatic enzyme inducers
inflammatory bowel disease, malabsorption and coeliac disease	aromatase inhibitors for breast cancer
epilepsy	long-term depot medroxyprogesterone acetate (DMPA)
endocrine diseases (eg, hypogonadism, Cushing's syndrome, hyperthyroidism, hyperparathyroidism)	androgen deprivation therapy for prostate cancer
chronic liver disease	proton pump inhibitors (PPIs)
neurological diseases (including Alzheimer's disease, Parkinson's disease, multiple sclerosis, stroke)	oral corticosteroids
moderate to severe chronic kidney disease	thiazolidinediones
chronic cardiopulmonary diseases	long-term heparin
depression	excessive thyroid hormone
asthma	medicines that increase the risk of falls (eg, sedating and blood pressure lowering medicines)
immobility or factors that increase the risk of falls (eg, balance disorder, visual impairment, sarcopenia)	
anorexia nervosa and other causes of low body weight	

‡‡ Refer to the MBS for a full list of restriction criteria.

§§ This is not an exhaustive list.

Available online with references at
www.nps.org.au/osteoporosis-medicines-tables

TABLE 4

Considerations for using PBS-listed osteoporosis medicines[1-3,7,8]

	PRECAUTIONS[III] FOR USE AND ADMINISTRATION	MEDICINE (BRAND NAME)[¶¶]	CONSIDERATIONS/ CONTRAINDICATIONS[III]
ANTIRESORPTIVE: BISPHOSPHONATE	**Bisphosphonates – general** Not for use with other antiresorptive or anabolic agents. Consider dental assessment, complete any dental procedures before starting, especially in patients with cancer or other risk factors for ONJ.		Consider the possibility of femoral fracture if the patient develops thigh, hip or groin pain. If an atypical femoral fracture (AFF) is identified, stop treatment and check contralateral femur.
	Bisphosphonates – oral (alendronate, risedronate) Advise patients to: ▶ take in the morning before food or drink*** ▶ remain upright until after eating ▶ avoid antacids, calcium, iron or mineral supplements within 2 hours (may interfere with absorption) ▶ stop tablets and seek help if experiencing pain on swallowing, or new or worsening heartburn.	**alendronate** Alendro Once Weekly, Alendrobell, Densate, Fonat, Ossmax, other generic brands	Contraindicated in patients with hypocalcaemia. Not recommended when CrCl < 35 mL/minute. Not for use in patients who are unable to stand or sit upright for at least 30 minutes. Contraindicated in patients with active upper GI tract disorders.
		risedronate Actonel, Actonel EC*** Once-a-Week, Acris Once-a-Week, Risedro once a week, Acris Once-a-Month, Actonel Once-a-Month, other generic brands	Not recommended when CrCl < 30 mL/minute. Not for use in patients who are unable to stand or sit upright for at least 30 minutes. Contraindicated in patients with active upper GI tract disorders.
	Bisphosphonate – IV (zoledronic acid) Give IV infusion over at least 15 minutes. Ensure patient is adequately hydrated before use. Monitor plasma concentration of calcium, phosphate and magnesium during treatment. Monitor renal function for delayed effects.	**zoledronic acid** Aclasta	Not recommended when CrCl < 35 mL/minute. Measure serum creatinine before each dose; if renal function deteriorates, withhold further dosing until serum creatinine returns to within 10% of baseline value unless there is life-threatening hypercalcaemia; restart at the same dose given before treatment interruption.
ANTIRESORPTIVE: BISPHOSPHONATE COMBINATIONS	Precautions as for Bisphosphonate - oral (above)	**alendronate with colecalciferol** Alendrobell plus D3, FonatPlus, Fosamax Plus, Alendrobell plus, Dronalen Plus, FonatPlus, Fosamax Plus , other generic brands	Vitamin D is contraindicated in hypercalcaemia, use with caution in patients with hyperphosphataemia. Contraindications as for alendronate above.
	Precautions as for Bisphosphonate - oral (above)	**alendronate with colecalciferol and calcium** Dronalen Plus D-Cal, Fosamax Plus D-Cal, ReddyMax Plus D-Cal, other generic brands	Vitamin D is contraindicated in hypercalcaemia, use with caution in patients with hyperphosphataemia. Contraindications as for alendronate above.
	Precautions as for Bisphosphonate - oral (above)	**risedronate and calcium** Acris Combi, Actonel EC Combi	Contraindications as for risedronate above.
	Precautions as for Bisphosphonate - oral (above)	**risedronate and calcium with colecalciferol** Actonel EC Combi D	Vitamin D is contraindicated in hypercalcaemia, use with caution in patients with hyperphosphataemia. Contraindications as for risedronate above.
ANTIRESORPTIVE: ANTI-RANKL	Ensure adequate intake of calcium and vitamin D; correct deficiency before use. Consider full dental assessment and complete any dental procedures before starting treatment to minimise risk of ONJ. Avoid invasive dental procedures during treatment.	**denosumab** Prolia	Contraindicated in patients with hypocalcaemia. Higher risk of hypocalcaemia in patients if CrCl < 30 mL/minute, and in patients on dialysis. Monitor calcium concentrations and for symptoms of hypocalcaemia. Consider the possibility of femoral fracture if the patient develops thigh, hip or groin pain. If AFF is identified, stop treatment and check contralateral femur.
ANTIRESORPTIVE / ANABOLIC	Strontium distribution in bone may falsely elevate BMD measurements. Ensure adequate intake of calcium and vitamin D; consider supplementation in patients with deficiencies. Best taken at bedtime, at least 2 hours after eating. Advise patients to mix the granules in water and drink immediately.	**strontium ranelate** Protos PBS subsidy removed August 2016	Increases risk of VTE – contraindicated if previous VTE or during prolonged immobilisation. Contraindicated if history of ischaemic heart disease, peripheral vascular disease, cerebrovascular disease, or if systolic BP > 160 mmHg or diastolic BP > 90 mmHg before or during treatment. Use cautiously in patients with cardiovascular risk factors (eg, hypertension, hyperlipidaemia, smoking, diabetes). Not for use in patients allergic to strontium or if CrCl < 30 mL/minute.
ANTIRESORPTIVE: SERM	Ensure adequate intake of calcium and vitamin D; consider supplementation in patients with deficiencies. Use with caution in women with or at risk of coronary heart disease – increased risk of VTE or fatal stroke.	**raloxifene** Evifyne, Evista, other generic brands	Increases risk of VTE – contraindicated if previous VTE, consider risk-benefit if other risk factors for VTE are identified. Stop raloxifene at least 3 days before and during prolonged immobilisation. Contraindicated for use in men. Avoid use in hepatic impairment. May cause endometrial proliferation – investigate unexplained uterine bleeding
PARATHYROID HORMONE	Ensure adequate intake of calcium and vitamin D; consider supplementation in patients with deficiencies. If measuring calcium concentration, take blood just before teriparatide injection as it may cause hypercalcaemia lasting several hours.	**teriparatide** Forteo	Contraindicated in patients with hyperparathyroidism. Combination treatment with alendronate not recommended. Avoid use when CrCl < 30 mL/minute. Lifetime maximum duration of 18 months due to risk of osteosarcoma.

ONJ – osteonecrosis of the jaw VTE – venous thromboembolism RANKL – receptor activator of nuclear factor kappa-B ligand SERM – selective oestrogen receptor modulator

[III] For a comprehensive list of precautions and contraindications, refer to the Product Information. ¶¶ Information current as at 4 August 2015. *** Actonel enteric-coated (Actonel EC) formulation may be taken with or without food.

www.nps.org.au
Level 7/418A Elizabeth Street Surry Hills NSW 2010
PO Box 1147 Strawberry Hills NSW 2012
02 8217 8700 02 9211 7578 info@nps.org.au

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