

6.09 DENOSUMAB Injection 60 mg in 1mL pre-filled syringe Prolia[®], Amgen Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a change to the PBS listing for denosumab to allow initiation of treatment of osteoporosis by nurse practitioners.

2 Requested listing

- 2.1 The submission requested the following changes to the existing listing for osteoporosis and established osteoporosis.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
DENOSUMAB 60mg/mL injection, 1 mL syringe	1	0	\$270.82	Prolia [®]	Amgen

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Osteoporosis
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
Population criteria:	Patient must be aged 70 years or older.
Prescriber Instructions	The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.
Administrative Advice	Continuing therapy only For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. Note: Antiresorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

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Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Established osteoporosis
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have fracture due to minimal trauma, AND Patient must not receive concomitant treatment with any other PBS-subsidised antiresorptive agent for this condition.
Prescriber Instructions	The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
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For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

- 3.1 Denosumab is TGA registered for the treatment of osteoporosis in postmenopausal women, as treatment to increase bone mass in men with osteopaenia receiving androgen deprivation therapy, and as treatment to increase bone mass in men with osteoporosis at increased risk of fracture.
- 3.2 At the July 2010 meeting, the PBAC recommended an authority required listing of denosumab pre-filled syringe 60 mg in 1 mL on a cost-minimisation basis compared with zoledronic acid. Denosumab was PBS listed from 1 December 2010.
- 3.3 At the November 2011 meeting, the PBAC recommended a change to the listing of denosumab from Authority Required to Authority Required (STREAMLINED), and recommended that the medicine was suitable for prescribing by nurse practitioners for continuing therapy only, where the therapy has been initiated by a medical

practitioner. The inclusion of nurse practitioner prescribing for continuing therapy only was considered appropriate as this was consistent with denosumab 120 mg/1.7 mL injection for the treatment of bone metastases.

- 3.4 The submission provided letters of support for this amendment from the Australian College of Nurse Practitioners and Endocrine Nurses' Society of Australia.
- 3.5 Currently, nurse practitioners are able to initiate and continue osteoporosis treatment with alendronate, risedronate and raloxifene. Nurse practitioners are not able to prescribe zoledronic acid.

For more detail on PBAC's view, see section 5 "PBAC outcome"

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

- 4.3 The minor submission provided updated long term data from the FREEDOM open-label extension study, with data now collected for up to 10 years of continuous denosumab use, demonstrating that efficacy and safety are similar to those observed in the initial 3 year FREEDOM trial. These results were not evaluated in the context of a minor submission.

Economic analysis

- 4.4 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

- 4.5 The minor submission considered that an increase in the utilisation of denosumab would be unlikely and therefore that the proposed change would have no financial impact on the PBS.

For more detail on PBAC's view, see section 5 "PBAC outcome"

5 PBAC Outcome

- 5.1 The PBAC recommended a change to the PBS listing for denosumab to allow

initiation of treatment of osteoporosis by nurse practitioners. In making this recommendation, the PBAC considered that there were no particular issues in the initiation of denosumab that could justify excluding nurse practitioner prescribing.

- 5.2 The PBAC considered that the factors which should be taken into consideration when initiating denosumab are no more complex than for osteoporosis treatments currently available to be initiated by nurse practitioners such as oral bisphosphonates and raloxifene, and agreed that the prescriber types should be aligned.
- 5.3 The PBAC noted the updated long-term data from the FREEDOM open-label extension study, which demonstrated that efficacy and safety are likely to be similar to that observed in the initial 3 year FREEDOM trial.
- 5.4 The PBAC considered that an increase in the utilisation of denosumab would be unlikely and therefore that the proposed change would be likely to have no financial impact on the PBS.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review as it has received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 Amend existing listing as follows:

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7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to

recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

Nurse Practitioners play an important role in the management of osteoporosis and Amgen welcomes the recommended change to the PBS listing which will allow Nurse Practitioners to initiate denosumab treatment