Twice-yearly osteoporosis treatment Prolia® (denosumab) available on the PBS for postmenopausal women with osteoporosis

Australian women with postmenopausal osteoporosis – a chronic bone disease that weakens bones and makes them more likely to fracture – now have access to another treatment option as Prolia® (denosumab) is made available on the Pharmaceutical Benefits Scheme (PBS).

In Australia, more than 510,000 women have osteoporosis, with postmenopausal women at higher risk due to the rapid decline in oestrogen levels following the menopause.

Prolia is listed on the PBS for women aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

Many people living with osteoporosis stop their prescribed osteoporosis treatments prematurely, usually within two years, which means they do not receive the full therapeutic benefit. In many cases, poor compliance with therapy leads to a loss of fracture reduction benefit.

Prolia is given as an injection under the skin every six months and works by targeting the cells that break down bone (osteoclasts) thereby making bone less susceptible to osteoporotic fractures.

Common side effects include back pain, arthralgia (joint pain), hypertension, upper respiratory tract infection, pain in extremity (pain in arms and legs) and osteoarthritis.

Any bone in the body can be affected by osteoporosis, however, fractures mostly occur in the hip, spine and wrist and can lead to long-lasting pain, reduced mobility, loss of independence and, in some cases, death.

Fractures related to osteoporosis affect one-in-two women over 60 years and can have a significant impact on daily life. About 50 percent of people with one osteoporotic fracture will have another, and the risk of future fractures rises with each new fracture.

Adequate intake of calcium and vitamin D is recommended in the management of osteoporosis.

Safety Information
Precautions: Hypocalcaemia must be corrected prior to starting Prolia. Patients receiving Prolia may develop skin infections, any signs and symptoms of cellulitis should be treated.

* Prolia is the first RANK ligand inhibitor to be listed on the PBS
Osteonecrosis of the jaw has been reported rarely in clinical studies in patients receiving Prolia dose of 60 mg every 6 months for osteoporosis. Good oral hygiene practices should be maintained during treatment with Prolia.³

Contraindications: Hypocalcaemia. Hypersensitivity to denosumab, Chinese Hamster Ovary (CHO)-derived proteins or to any component of the medicine.³

The most common adverse events reported in studies of women with postmenopausal osteoporosis or low bone mass in 8,091 women, occurring in greater than or equal to 10% of patients either in the Prolia-treated or placebo group, were back pain (34.1% Prolia, 34.0% placebo), arthralgia (20.4% in each group), hypertension (15.3% Prolia, 16.1% placebo), nasopharyngitis (14.8% Prolia, 15.6% placebo), pain in extremity (11.8% Prolia, 11.2% placebo) and osteoarthritis (10.9% Prolia, 11.1% placebo).³

Adverse reactions defined as adverse events reported in at least 2% of postmenopausal women with osteoporosis or low bone mass (n = 8,091) and at least 1% more frequently in the Prolia®-treated than in the placebo-treated women were: hypercholesterolemia (7.0% Prolia®, 5.9% placebo) and eczema (includes dermatitis, allergic dermatitis, atopic dermatitis and contact dermatitis) (3.1% Prolia®, 1.7% placebo).³

In two phase III placebo-controlled clinical trials in postmenopausal women with osteoporosis, skin infections leading to hospitalisation were reported more frequently in the Prolia® (0.4%, 16 of 4,050) versus the placebo (0.1%, 3 of 4,041) groups, respectively. These cases were predominantly cellulitis. The overall incidence of skin infections was similar between the Prolia® (1.5%, 59 of 4,050) and placebo groups (1.2%, 50 of 4,041).³

Pancreatitis was reported in 4 patients (0.1%) in the placebo and 8 patients (0.2%) in the Prolia® groups. Several patients had a prior history of pancreatitis or a confounding event (e.g. gallstones). The time from product administration to event occurrence was variable.³

– ENDS –

Media release issued by SHJ on behalf of Amgen & GlaxoSmithKline Australia.

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References

3. Prolia® (denosumab) approved Product Information. 2 June 2010
5. Rossini M et al. Osteoporosis Int. 2006;17:914–921

PBS Information: This product is authority listed on the PBS as a treatment for postmenopausal osteoporosis. Refer to PBS Schedule for full information.

For more information about Prolia, please see the Consumer Medicine Information available at: www.medicines.org.au. Product Information (PI) available on request on 1800 646 998.

Please review full product information before prescribing.

MINIMUM PRODUCT INFORMATION

INDICATION: Treatment of osteoporosis in postmenopausal women to reduce risk of vertebral, nonvertebral and hip fractures. CONTRAINDICATIONS: Hypocalcaemia. Hypersensitivity to denosumab, CHO-derived proteins or any component. PRECAUTIONS: Correct hypocalcaemia prior to initiating therapy. Monitor calcium in patients predisposed to hypocalcaemia. Adequate intake of calcium and Vitamin D is important. ADVERSE EFFECTS: Hypocalcaemia, skin infections (predominantly cellulitis), pancreatitis, rarely jaw osteonecrosis. DOSAGE AND ADMINISTRATION: Single subcutaneous injection of 60mg, once every 6 months. Ensure adequate intake of calcium and vitamin D. No dose adjustment required in the elderly or in renal impairment. PRESENTATION: Prefilled syringe with automatic needle guard. PBS PRICE: $304.87 Approved PI, 2 June 2010.

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NOTES TO EDITORS:

Prolia is a registered Trademark of Amgen.
About Amgen
Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science’s promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people’s lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

About Denosumab Collaborations
In July 2009, Amgen and GlaxoSmithKline (GSK) announced a collaboration agreement to jointly commercialise Prolia for postmenopausal osteoporosis in Europe, Australia, New Zealand and Mexico once the product is approved in these countries. Amgen will commercialise Prolia’s postmenopausal osteoporosis in the United States and Canada.

In addition, GlaxoSmithKline will register and commercialize denosumab for all indications in countries where Amgen does not currently have a commercial presence, including China, Brazil, India and South Korea but excluding Japan. The structure of the collaboration allows Amgen the option of an expanded role in commercialization in both Europe and certain emerging markets in the future.

Amgen and Daiichi-Sankyo Company, Limited have a collaboration and license agreement for the development and commercialization of denosumab in Japan.

About GlaxoSmithKline
GlaxoSmithKline – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.