



## Recently Introduced Products

Drug Name	Indication	Potential Impact	Expected Avg. Annual Cost
Invega® Sustenna®	For the management of the manifestations of schizophrenia and related psychiatric disorders deficiency	\$	\$7,222.80

\$: Est. drug plan expenditure increase of <1%\* \$\$: Est. drug plan expenditure increase of 1-5%\* \$\$\$: Est. drug plan expenditure increase of >5%\*

## Prolia® – A Novel Biologic Treatment for Post-menopausal Osteoporosis

Prolia® (denosumab) is a new biologic agent used to treat osteoporosis in post-menopausal women. Osteoporosis is a metabolic bone disease that causes increasing bone fragility and risk of fractures due to low bone density and quality. Over the age of 50, 1 in 4 women and 1 in 8 men have osteoporosis. The higher incidence in post-menopausal women has been linked to low sex hormone levels (i.e. estrogen, progesterone) in the years following menopause. This results in an imbalance in the natural bone remodeling cycle where bone resorption (breakdown) overtakes bone formation. In Canada, osteoporosis affects approximately 1.8 million women<sup>1,2</sup>.

The primary goal of osteoporosis treatment is the prevention of fractures. Current drug therapies, taken in conjunction with calcium and vitamin D, target different components of the bone remodeling cycle. Prolia® restores bone mass and strength by inhibiting the development and activity of osteoclasts, the cells responsible for breakdown of the bone matrix<sup>2</sup>. According to clinical trials, Prolia® is comparable or superior in restoring bone mass to other osteoporosis treatments including the gold standard, oral bisphosphonates (e.g. Fosamax®, Actonel®, Aclasta®, etc). In addition, Prolia® has been demonstrated to help prevent all types of fractures including hip, vertebral and non-vertebral fractures<sup>1,2</sup>.

Prolia® is indicated in post-menopausal women at high risk of fractures or in those who have failed or not tolerated previous therapies. The recommended dose of Prolia® is one subcutaneous injection every six months. Prolia's twice per year vs. weekly administration with oral bisphosphonates may help increase compliance, resulting in better prevention of bone fractures. When compared to Aclasta® (an injectible bisphosphonate), Prolia® offers the advantage of subcutaneous injection as opposed to intravenous infusion, allowing patients with proper training to self-administer.

Prolia's annual cost of treatment is \$606.00, which is similar to that of Aclasta® (\$770). Prolia® is fully covered under Open Drug Formularies, the Specialty Drug Programs and ClaimSecure's Stoploss program. However, like Aclasta, it is placed under Special Authorization for ClaimSecure groups that subscribe to the Managed Formulary. With Special Authorization, ClaimSecure ensures the following: 1) the medication is used for its approved indication; 2) the member has tried less expensive oral medications (i.e. bisphosphonates), and 3) coordination of benefits with available senior Provincial drug programs.

If you require additional information about Prolia®, please contact Clinical Services Department, at (905) 949-2322 or 1-888-479-7587.

### Recommendation: Special Authorization

*ClaimSecure reserves the right to amend in part or in its entirety stated special authorization clinical guidelines*

#### References:

- 1) Prolia™ Private Payer Submission Binder. Amgen Canada Inc., August, 2010.
- 2) Serota, A.C Osteoporosis  
<http://emedicine.medscape.com/article/311449-overview>  
Accessed September 24, 2010.

