Prolia

Description

Prolia (denosumab)

Background

Prolia is used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and cannot use another osteoporosis medicine or other osteoporosis medicines did not work well. Prolia may also be used to increase bone mass in men with osteoporosis who are at high risk for fracture; treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body; and treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body. Additionally, Prolia is used to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture (1).

Regulatory Status

FDA-approved indications: Prolia is a RANK ligand (RANKL) inhibitor indicated for: (1)  
- Treatment of postmenopausal women with osteoporosis at high risk for fracture  
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture  
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture  
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer  
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia and patients must adequately supplement with calcium and vitamin D (1).

Prolia may cause fetal harm when administered to a pregnant woman. Prolia is contraindicated in women who are pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus (1).

Prolia may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture (1).

The safety and effectiveness of Prolia in pediatric patients has not been established (1).

**Related policies**
Xgeva

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Prolia may be considered **medically necessary** in patients 18 years of age and older to treat osteoporosis, breast cancer in female patients receiving aromatase-inhibitor therapy, or non-metastatic prostate cancer in male patients receiving androgen deprivation therapy and if the conditions indicated below are met.

Prolia may be considered **investigational** for patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Osteoporosis
2. Breast cancer in female patients receiving aromatase-inhibitor therapy
3. Non-metastatic prostate cancer in male patients receiving androgen deprivation therapy

AND ALL of the following for ALL diagnoses:
   a. Inadequate treatment response, intolerance, or contraindication to bisphosphonate therapy
   b. Pre-existing hypocalcemia must be corrected prior to initiating therapy
   c. High risk for bone fracture(s)
   d. NO concurrent therapy with another RANKL-inhibitor (see Appendix 1)
   e. NO concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 2)

Prior – Approval Renewal Requirements

Age
   18 years of age or older

Diagnoses

Patient must have ONE of the following:

   1. Osteoporosis
   2. Breast cancer in female patients receiving aromatase-inhibitor therapy
   3. Non-metastatic prostate cancer in male patients receiving androgen deprivation therapy

AND the following for ALL diagnoses:
   a. NO concurrent therapy with another RANKL-inhibitor (see Appendix 1)
   b. NO concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 2)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity   2 syringes/ vials per 12 months
**Section**: Prescription Drugs

**Effective Date**: October 1, 2019

**Subsection**: Endocrine and Metabolic Drugs

**Original Policy Date**: December 19, 2014

**Subject**: Prolia

**Page**: 4 of 6

---

**Duration**: 12 months

**Prior – Approval Renewal Limits**

Same as above

---

**Rationale**

**Summary**

Prolia is an osteoclast inhibitor used to treat osteoporosis, breast cancer in female patients receiving aromatase-inhibitor therapy, or non-metastatic prostate cancer in male patients receiving androgen deprivation therapy and who are at high risk of bone fractures and not receiving Xgeva. It may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture. The safety and effectiveness of Prolia in pediatric patients has not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Prolia while maintaining optimal therapeutic outcomes.

**References**


---

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2014</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2015</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Removal of high risk of bone fracture from renewal</td>
</tr>
<tr>
<td></td>
<td>Addition of inadequate treatment response, intolerance, or contraindication to bisphosphonate therapy and quantity of 2 syringes per year, per PMPC</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual review</td>
</tr>
<tr>
<td>September 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Addition of the age requirement to the renewal section</td>
</tr>
<tr>
<td>August 2018</td>
<td>Update of regulatory section per package insert: treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review and reference update</td>
</tr>
</tbody>
</table>
Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Endocrine and Metabolic Drugs  Original Policy Date: December 19, 2014
Subject: Prolia  Page: 5 of 6

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.
### Appendix 1 - List of RANKL Inhibitors

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>denosumab</td>
<td>Prolia</td>
</tr>
<tr>
<td>denosumab</td>
<td>Xgeva</td>
</tr>
</tbody>
</table>

### Appendix 2 - List of PA Osteoporosis Medications

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>abaloparatide</td>
<td>Tymlos</td>
</tr>
<tr>
<td>denosumab</td>
<td>Prolia</td>
</tr>
<tr>
<td>romosuzumab-aqqg</td>
<td>Evenity</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>Forteo</td>
</tr>
</tbody>
</table>