

**RX.PA.028.MPC Osteoporosis Injectables Policy**

The purpose of this policy is to define the prior authorization process for specialty injectables utilized in the treatment of various types of osteoporosis or osteopenia.

**DEFINITIONS**

Medication	PMO	OS	OM	OP
Evenity (ronosozumab – aqgg)	X			
Prolia (denosumab)	X	X	X	
Reclast (zoledronic acid)	X	X	X	X
<ul style="list-style-type: none"> <li>• PMO – Postmenopausal osteoporosis</li> <li>• OS – Osteoporosis due to steroid use</li> </ul>		<ul style="list-style-type: none"> <li>• OM – Male osteoporosis</li> <li>• OP – Osteopenia</li> </ul>		

**Preferred vs Non-Preferred**

	Medications
Preferred	<ul style="list-style-type: none"> <li>• Reclast® (zoledronic acid)</li> </ul>
Non-preferred	<ul style="list-style-type: none"> <li>• Evenity® (ronosozumab-aqgg)</li> <li>• Prolia® (denosumab)</li> </ul>

- Requests for non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Eviti reviews prior authorization requests for all oncology related indications for osteoporosis products.

**PROCEDURE**

**A. Initial Authorization Criteria:**

*Must meet all the criteria listed under the respective diagnosis:*

**For all diagnoses:**

- Must not currently be using more than one osteoporosis injectable simultaneously
- Must have documentation of adequate calcium and vitamin D supplementation

### 1. Postmenopausal osteoporosis or male osteoporosis

- Must have diagnosis of osteoporosis
- Must be a postmenopausal female or male  $\geq 50$  years old
- Documentation of trial and failure of at least 1-year or intolerance to at least ONE oral bisphosphonate or a documented medical reason (hypersensitivity, contraindication, etc.) for not utilizing oral bisphosphonate therapy.
- Must have documentation of at least one of the following:
  - Bone mineral density (BMD) T-score  $\leq -2.5$
  - BMD T-score of -1.0 to -2.5 at the femoral neck or lumbar spine and a 10-year probability of a hip fracture  $>3\%$  or a 10-year probability of a major osteoporosis-related fracture  $>20\%$  based on the U.S. adapted World Health Organization (WHO) algorithm
  - History of osteoporotic fracture
- For Evenity only:
  - Must not have had previous stroke or myocardial infarction within the past year. Consider if benefits outweigh the risks in patients with significant cardiovascular risk factors.

### 2. Prevention of osteoporosis in postmenopausal females

- Must have a diagnosis of osteopenia
- Must be a postmenopausal female
- Documentation of trial and failure of at least 1-year or intolerance to at least ONE oral bisphosphonate or a documented medical reason (hypersensitivity, contraindication, etc.) for not utilizing oral bisphosphonate therapy.
- Must have a documented BMD T-score of -1.0 to -2.5

### 3. Treatment or prevention of osteoporosis due to corticosteroid use

- Documentation of chronic (12+ month(s)) steroid therapy with an average daily dose of  $\geq 7.5$  mg/day
- Documentation of trial and failure of at least 1-year or intolerance to at least ONE oral bisphosphonate or a documented medical reason (hypersensitivity, contraindication, etc.) for not utilizing oral bisphosphonate therapy.

### 4. Women receiving aromatase inhibitor therapy or men receiving androgen deprivation therapy at high risk for fracture

- Must have documentation of at least one of the following:
  - Bone mineral density (BMD) T-score  $\leq -2.5$

- BMD T-score of -1.0 to -2.5 at the femoral neck or lumbar spine and a 10-year probability of a hip fracture >3% or a 10-year probability of a major osteoporosis-related fracture >20% based on the U.S. adapted World Health Organization (WHO) algorithm
- History of osteoporotic fracture
- Documentation of trial and failure of at least 1 year or intolerance to at least one oral generic bisphosphonate unless contraindicated

**B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling.**

**C. Osteoporosis injectable treatments will be considered investigational or experimental for any other use and will not be covered.**

**D. Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
  - Member has experienced clinical benefit as evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

**Limitations:**

Length of Authorization (if above criteria met)	
Initial Authorization	<ul style="list-style-type: none"> <li>• <b>Prolia:</b> 6 months</li> <li>• <b>Evenity:</b> If member has already started therapy, then the approval duration should only allow for a maximum of 12 months of treatment based on the start date of treatment</li> <li>• <b>Reclast Treatment:</b> 12 months</li> <li>• <b>Reclast Prevention:</b> 24 months</li> </ul>
Reauthorization	<ul style="list-style-type: none"> <li>• <b>Prolia:</b> 12 months</li> <li>• <b>Evenity:</b> No reauthorizations granted for Evenity</li> <li>• <b>Reclast Treatment:</b> 12 months</li> <li>• <b>Reclast Prevention:</b> 24 months</li> </ul>
Quantity Level Limits	
Prolia	<ul style="list-style-type: none"> <li>• 2 injections per year</li> </ul>
Reclast	<ul style="list-style-type: none"> <li>• Treatment: 1 infusion per year</li> <li>• Prevention: 1 infusion every 2 years</li> </ul>

**Codes: J Code(s)**

Code	Description
J0897	Injection, denosumab, 1 mg
J3489	Injection, zoledronic acid, 1mg
J3111	Injection, romosozumab-aqqg, 1mg

**REFERENCES**

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Manufacturing; May 2018.
2. Evenity [package insert]. Thousand Oaks, CA: Amgen Manufacturing; April 2019.
3. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.

## REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/2026</i>
<i>Annual Review</i>	<i>02/2025</i>
<i>Annual Review</i> <i>Change in Non-MPC renewal to renewal from previous insurer</i>	<i>02/2024</i>
<i>Update to preferred vs non-preferred verbiage</i>	<i>03/2023</i>
<i>Annual review</i>	<i>02/2023</i>
<i>Addition of Evenity and Reclast. Inclusion of osteopenia criteria and preferred vs non-preferred medications</i>	<i>01/2023</i>
<i>Selected Revision</i> <i>Addition of MPC vs Non-MPC Renewal. Removal of several pharmacy benefit medications (Tymlos, Evenity, Forteo)</i>	<i>10/2022</i>
<i>Annual review</i>	<i>02/2022</i>
<i>Addition of dosing requirements and off-label restrictions</i>	<i>12/2021</i>
<i>P&amp;T Review</i>	<i>11/2021</i>