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 – aqqg)	X			
Prolia (Denosumab) & Denosumab Biosimilars	X	X	X	
Reclast (zoledronic acid)	X	X	X	X
Ibandronate	X			
• PMO – Postmenopausal osteoporosis • OS – Osteoporosis due to steroid use		• OM – Male osteoporosis • OP – Osteopenia		

Preferred vs Non-Preferred

	Medications
Preferred	• **Reclast® (zoledronic acid)** • **Denosumab-nxxp (Bildyos)**
Non-preferred	• **Evenity® (ronosozumab-aqqg)** • **Prolia® (Denosumab) & other Denosumab Biosimilars** • **Ibandronate**

- 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 ≥ 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 ≤ -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 ≥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 ≤ -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. <u>Reauthorization Criteria:</u>

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

<u>Limitations:</u>

Length of Authorization (if above criteria met)	
Initial Authorization	• **Prolia (Denosumab) & Denosumab Biosimilars**: 6 months • **Evenity:** 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 • **Reclast Treatment:** 12 months • **Reclast Prevention:** 24 months

Reauthorization	• **Prolia (Denosumab) & Denosumab Biosimilars :** 12 months • **Evenity:** No reauthorizations granted for Evenity • **Reclast Treatment:** 12 months • **Reclast Prevention:** 24 months
Quantity Level Limits	
Prolia (Denosumab) & Denosumab Biosimilars	• 2 injections per year
Reclast	• Treatment: 1 infusion per year • Prevention: 1 infusion every 2 years
Ibandronate	• 4 injections per year

Codes: J Code(s)

Code	Description
J0897	Injection, denosumab, 1 mg
J3489	Injection, zoledronic acid, 1mg
J3111	Injection, romosozumab-aqqg, 1mg
J1740	Injection, ibandronate sodium, 1mg
Q5161	Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1mg
Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1mg
Q5157	Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1mg
Q5158	Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1mg
Q5159	Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1mg
Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 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.
4. Ibandronate [package insert]. India: Gland Pharma Limited; Jan 2026.
5. Enoby [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; Sept 2025.
6. Bosaya [package insert]. Cambridge, MA: Biocon Biologics Inc.; Sept 2025.
7. Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; Oct 2025.
8. Stoboclo [package insert]. Incheon, Republic of Korea: Celltrion Inc.; Oct 2025.
9. Bomyntra [package insert]. Lkae Zurich, IL: Fresenius Kabi USA, LLC; Mar 2025.
10. Ospomyv [package insert]. Incheon, Republic of Korea: Samsung Bioepis Co., Ltd.; Oct 2025.
11. Bildyos [package insert]. Shengrong Road, China: Shanghai Henlius Biotech, Inc.; Aug 2025.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Selected Revision *Addition of ibandronate and denosumab biosimilars*	*05/2026*
Annual Review	*02/2026*
Annual Review	*02/2025*
Annual Review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Update to preferred vs non-preferred verbiage	*03/2023*
Annual review	*02/2023*
Addition of Evenity and Reclast. Inclusion of osteopenia criteria and preferred vs non-preferred medications	*01/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal. Removal of several pharmacy benefit medications (Tymlos, Evenity, Forteo)*	*10/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2021*