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
Prolia (denosumab)	X	X	X	X

- PMO – Postmenopausal osteoporosis
- OS – Osteoporosis due to steroid use
- OM – Male osteoporosis
- OP – Osteopenia

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 injectablesimultaneously
- Must have 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 oralbisphosphonate or a documented medical reason (hypersensitivity, contraindication, etc.) for not utilizing oral bisphosphonate therapy.
- Must meet 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

2. Treatment or prevention of osteoporosis due to corticosteroid use (Requestfor Prolia)

- Documentation of chronic (12+ month) steroid therapy with an average daily dose of ≥5 mg/day

- Documentation of trial and failure of at least 1-year or intolerance to at least ONE oralbisphosphonate or a documented medical reason (hypersensitivity, contraindication, etc.) for not utilizing oral bisphosphonate therapy.

3. Women receiving aromatase inhibitor therapy or men receiving androgendeprivation therapy at high risk for fracture (Request for Prolia)

- Must meet 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
- Must have tried and failed or be intolerant to at least one oral genericbisphosphonate 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-yearintervals based upon:

<u>MPC Renewal:</u>

- 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

<u>Non-MPC Renewal:</u>

- Members who have previously been taking the requested drug and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for the requested drug;

AND

- 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	Up to 1 year
Reauthorization	Up to 1 year
Quantity Level Limits	
Prolia	• 2 injections per year

If the established criteria are not met, the request is referred to a Medical Director for review.

Codes: J Code(s)

Code	Description
J0897	Injection, denosumab, 1 mg

REFERENCES

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Manufacturing; May 2018.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
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*