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

PREFERRED – PA required				
Medication	PMO	OS	OM	OP
Tymlos (abaloparatide)	X			
NON-PREFERRED – PA required				
Medication	PMO	OS	OM	OP
Forteo (teriparatide)	X	X	X	
Evenity (ronosozumab – aqqg)	X			
Prolia (denosumab)	X	X	X	X

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

PROCEDURE

If the requested medication is intended to be processed under home infusion or medical, then please dismiss the case and route to Maryland Physicians Care Medical UM; Fax: 1-800-953-8856.

*Pharmacy Example: A pharmacy is processing the claim and providing the medication to the member to administer, for the member to take to their prescriber to administer, or for the pharmacy to deliver directly to the prescriber to administer. **Prescriber is not buying a billing***

Home Infusion Example: Medication is administered in the member's home by a home infusion provider.

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 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 or intolerance to at least ONE oral bisphosphonate 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
- Non-preferred products:
    - Must have documentation of a previous trial and failure, contraindication or intolerance to a preferred product indicated for diagnosis
- 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. Treatment or prevention of osteoporosis due to corticosteroid use (Request for Prolia or Forteo only)

- Documentation of chronic (12+ month) steroid therapy with an average daily dose of ≥5 mg/day
- Documentation of trial and failure or intolerance to at least ONE oral bisphosphonate or a documented medical reason (hypersensitivity, contraindication, etc.) for not utilizing oral bisphosphonate therapy.
- Non-preferred products:
    - Must have documentation of a previous trial and failure, contraindication or intolerance to a preferred product indicated for diagnosis

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

- 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 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 chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

- Maximum of 24 months of therapy with Forteo and/or Tymlos
- No reauthorizations granted for Evenity

*** Forteo reauth requests must have documentation of a previous trial and failure, contraindication or intolerance to a preferred product indicated for diagnosis***

<u>Limitations:</u>

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year • **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 • **Forteo and/or Tymlos:** If member has already started therapy with Forteo and/or Tymlos more than 1 year ago, then the approval duration should only allow for a maximum of 24 months of treatment based on the start date of treatment
Reauthorization	Up to 1 year • **Evenity:** No reauthorizations granted for Evenity • **Forteo and/or Tymlos:** Total duration of therapy shall not exceed 24 months
Quantity Level Limits	
Forteo Tymlos	• Forteo: 1 pen per 28 days • Tmylos: 1 pen per 25 days • Cumulative lifetime use may not exceed 2 years
Prolia	• 2 injections per year

Evenity	• 2 injections per 28 days • Cumulative lifetime use may not exceed 1 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. Forteo [package insert]. Eli Lilly and Company; Indianapolis, IN: January 2010.
2. Evista [package insert]. Indianapolis, IN: Eli Lilly and Co; January 2011.
3. Prolia [package insert]. Thousand Oaks, CA: Amgen Manufacturing; May 2018.
4. Evenity [package insert]. Thousand Oaks, CA: Amgen Manufacturing; April 2019.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2021*