Clinical Policy: Bone Density Regulators

Reference Number: PHW.PDL.060
Effective Date: 01/01/2020
Last Review Date: 11/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Bone Density Regulators are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Bone Density Regulators

A. Prescriptions That Require Prior Authorization

Prescriptions for Bone Density Regulators that meet any of the following conditions must be prior authorized:

1. A non-preferred Bone Density Regulator.

2. A preferred bone-modifying monoclonal antibody.

3. A Bone Density Regulator with a prescribed quantity that exceeds the quantity limit.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bone Density Regulator, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is prescribed the Bone Density Regulator for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication,

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
3. Does not have a history of a contraindication to the prescribed drug,

4. For an osteoporosis-related condition, was evaluated for secondary causes of osteoporosis including complete blood count (CBC), vitamin D, ionized calcium, phosphorus, albumin, total protein, creatinine, liver enzymes (specifically alkaline phosphatase), intact parathyroid hormone (PTH), thyroid stimulating hormone (TSH), urinary calcium excretion, and testosterone (if a male), **AND**

5. For an anabolic agent, **all** of the following:

a. **One** of the following:
   i. Has a T-score of -3.5 or below, a T-score of -2.5 or below and a history of fragility fracture or multiple vertebral fractures
   ii. Has a history of therapeutic failure,[1] intolerance, or contraindication to bisphosphonate,

b. Has not received a cumulative treatment duration that exceeds recommendations in the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

c. For Forteo (teriparatide) and Tymlos (abaloparatide), does not have **any** of the following:
   i. Paget's disease,
   ii. Bone metastases,
   iii. A history of skeletal malignancies,
   iv. Metabolic bone disease other than osteoporosis,
   v. A hypercalcemic disorders,
   vi. Unexplained elevations of alkaline phosphatase,
   vii. Open epiphyses,
   viii. Prior external beam or implant radiation therapy involving the skeleton,

d. For Evenity (romosozumab), does not have a history of myocardial infarction or stroke,

e. For Evenity (romosozumab) or Tymlos (abaloparatide), has a documented history of intolerance or contraindication to teriparatide,

f. For Forteo (teriparatide) and Bonsity (teriparatide), has a contraindication or an intolerance to generic teriparatide that would not be expected to occur with the reequested drug, **AND**

6. For Evista (raloxifene), **all** of the following:

   a. Does not have a history of venous thromboembolic events or breast cancer,

   b. For women with a risk factor for stroke (such as prior stroke or transient ischemic attack (TIA), atrial fibrillation, hypertension, or cigarette smoking), the increased risk of death due to stroke has been discussed with the member and documented by the prescriber,

   c. **One** of the following:

[1] Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate.

i. Is a postmenopausal woman at high risk of fracture[2] and high risk for invasive breast cancer as defined by **one** of the following:
   a) Prior biopsy with lobular carcinoma in situ (LCIS) or atypical hyperplasia,
   b) One or more first degree relatives with breast cancer,
   c) A 5-year predicted risk of breast cancer ≥ 1.66% (based on the modified Gail model),

ii. Is a postmenopausal woman at high risk of fracture[2] with a history of therapeutic failure,**Error! Bookmark not defined.** intolerance, or contraindication to oral bisphosphonates,

7. For all other Bone Density Regulators, **one** of the following:

   a. The request is for a denosumab 120 mg/1.7 mL product

   b. The request is not for a denosumab 120 mg/1.7 mL product and **all** of the following:

      i. Is at high risk of fracture,**Error! Bookmark not defined.**
      ii. Has a documented history of therapeutic failure**Error! Bookmark not defined.** of or a contraindication or an intolerance to the preferred Bone Density Regulators approved or medically accepted for the member's diagnosis,
      iii. For a parenteral bisphosphonate, has a contraindication or an intolerance to oral bisphosphonates;

AND

8. For a non-preferred Bone Density Regulator with a therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic that would not be expected to occur with the requested drug;

9. If a prescription for a Bone Density Regulator is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

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[1] Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate

[2] High risk is defined as one of the following: T-score between -1.0 and -2.5 and a history of fragility fracture of the proximal humerus, pelvis, or distal forearm; T-score between -1.0 and -2.5 at the femoral neck, total hip, 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 US-adapted World Health Organization (WHO) algorithm; T-score -2.5 or below at the femoral neck, total hip, or lumbar spine; OR history of low-trauma spine or hip fracture, regardless of bone density.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPITONS FOR BONE DENSITY REGULATORS:
The determination of medical necessity of a request for renewal of a prior authorization for Bone Density Regulator that was previously approved will take into account whether the member:

1. Based on the prescriber's assessment, the member's condition has stabilized and/or the member continues to benefit from the prescribed Bone Density Regulator; **AND**

2. For a non-preferred Bone Density Regulator with a therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic that would not be expected to occur with the requested drug; **AND**

3. If a prescription for a Bone Density Regulator is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bone Density Regulator. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. **Dose and Duration of Therapy**

Requests for prior authorization of Bone Density Regulators will be approved as follows:

1. Initial and renewal requests for prior authorization of Bone Density Regulators will be approved for up to 12 months.

2. Prior authorization of Forteo (teriparatide) and Tymlos (abaloparatide) will be limited to 2 years cumulative duration of treatment.

3. Prior authozization of Evenity (romosozumab) to 12 months cumulative duration of treatment.

E. References:

1. Eastell, R, Rosen, R.J, et.al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society* Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism*. (2019) 104:1595–1622.
2. Dolores Shoback, Clifford J Rosen, Dennis M Black, Angela M Cheung, M Hassan Murad, Richard Eastell, Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, *The Journal of Clinical Endocrinology & Metabolism*, Volume 105, Issue 3, March 2020, Pages 587–594.
3. Cosman, F, de Beur, S.J, et.al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporosis International.* (2014) 25:2359–2381.
4. Buckley, L, Guyatt, G, et.al. 2017 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis & Rheumatology.* (2017) 69:1521-1537.
5. Forteo (teriparatide) Prescribing Information. Indianapolis, IN; Lilly; October 2016.
6. Tymlos (abaloparatide) Prescribing Information. Waltham, MA; Radius Health, Inc. October 2018.
7. Reclast (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; July 2017.
8. Zometa (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2018.
9. Evista (raloxifene) Prescribing Information. Indianapolis, IN; Lilly; June 2018.
10. Xgeva (denosumab) Prescribing Information. Thousand Oaks, California; Amgen Inc; June 2018.
11. Rosen, C.J. Parathyroid hormone/parathyroid hormone-related protein analogs for osteoporosis. UpToDate. Accessed April 22, 2019.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020

Reviews, Revisions, and Approvals	Date
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024.	11/2023
Q1 2025 annual review: no changes.	11/2024
Q1 2026: policy revised according to DHS revisions effective 01/05/2026.	11/2025