Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2020**
Policy Number: PHW.PDL.060	**Effective Date: 01/05/2021** **Revision Date: 11/2020**
Policy Name: Bone Density Regulators	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021: policy revised according to DHS revisions effective 01/05/2021.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Bone Density Regulators

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

Revision Log

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 health plans affiliated with PA Health and 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. See the Preferred Drug List (PDL) for the list of preferred Bone Density Regulators at: https://papdl.com/preferred-drug-list.

2. 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 beneficiary:

1. For a non-preferred Bone Density Regulator, **all** of the following:

   a. 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,

   b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

   c. Does not have a history of a contraindication to the prescribed medication,

   d. 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),

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

   i. **One** of the following:
      a) 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
      b) Has a history of therapeutic failure,[1] intolerance, or contraindication to bisphosphonate.

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

   iii. For Forteo (teriparatide) and Tymlos (abaloparatide), does not have a history of **any** of the following:
      a) Paget's disease,
      b) Bone metastases,
      c) Skeletal malignancies,
      d) Metabolic bone disease other than osteoporosis,
      e) Hypercalcemic disorders,
      f) Unexplained elevations of alkaline phosphatase,
      g) Open epiphyses,
      h) Prior external beam or implant radiation therapy involving the skeleton,

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

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

   vi. For teriparatide, has a contraindication or intolerance to Forteo that would not be expected to occur with teriparatide,

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

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

   ii. 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 beneficiary and documented by the prescriber,

[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.

iii. **One** of the following:

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

b) 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,

g. For Xgeva (denosumab), **one** of the following:

i. Has a history of therapeutic failure, intolerance, or contraindication to the preferred zoledronic acid,
ii. Is being treated for giant cell tumor of the bone,

h. For all other non-preferred Bone Density Regulators, **all** of the following:

i. Is at high risk of fracture[2],
ii. Has a documented history of therapeutic failure[1], intolerance, or contraindication to the preferred Bone Density Regulators approved for the beneficiary's diagnosis,
iii. For a parenteral bisphosphonate, has a documented history of contraindication or intolerance to oral bisphosphonates;

AND

2. 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 beneficiary 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 beneficiary, the request for prior authorization will be

[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.

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 beneficiary:

1. Based on the prescriber's assessment, continues to benefit from the prescribed Bone Density Regulator; **AND**

2. 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 beneficiary 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 beneficiary, 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 beneficiary.

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. PA Health & Wellness will limit authorization of Forteo (teriparatide) and Tymlos (abaloparatide) to 2 years cumulative duration of treatment.

3. PA Health & Wellness will limit authorization 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