

<b>ISSUE DATE</b>  November 6, 2020	<b>EFFECTIVE DATE</b>  January 5, 2021	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Bone Density Regulators – Pharmacy Services		<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Bone Density Regulators submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Bone Density Regulators will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Bone Density Regulators to the appropriate managed care organization.

*01-20-14	09-20-13	27-20-09	33-20-10
02-20-07	11-20-07	30-20-06	
03-20-07	14-20-08	31-20-14	
08-20-17	24-20-08	32-20-06	

<p><b>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</b></p> <p>The appropriate toll-free number for your provider type.</p> <p>Visit the Office of Medical Assistance Programs website at  <a href="https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx">https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx</a>.</p>
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**BACKGROUND:**

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

**DISCUSSION:**

During the August 11, 2020, meeting, the P&T Committee recommended revisions to the guidelines to determine medical necessity of Bone Density Regulators to reflect recent updates to the Endocrine Society consensus guidelines for the Pharmacological Management of Osteoporosis in Postmenopausal Women and to address the recent U.S. Food and Drug Administration approval of Evenity (romosozumab).

The revisions to the guidelines to determine medical necessity of Bone Density Regulators, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Bone Density Regulators are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Bone Density Regulators) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

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**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. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

**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,<sup>1</sup> intolerance, or contraindication to

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<sup>1</sup> 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.

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bisphosphonates,

- 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,
  - iii. **One** of the following:
    - a) Is a postmenopausal woman at high risk of fracture<sup>2</sup> and high risk for invasive

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<sup>1</sup> 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

<sup>2</sup> 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  $\geq 3\%$  or a 10-year probability of a major osteoporosis-related fracture  $\geq 20\%$  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.

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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  $\geq 1.66\%$  (based on the modified Gail model)

b) Is a postmenopausal woman at high risk of fracture with a history of therapeutic failure,<sup>1</sup> 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,<sup>2</sup>
- ii. Has a documented history of therapeutic failure,<sup>1</sup> 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 Quantity Limits Chapter.

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.

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 Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the

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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. The Department will limit authorization of Forteo (teriparatide) and Tymlos (abaloparatide) to 2 years cumulative duration of treatment.
3. The Department 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.

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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.