Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 preferred bone-modifying monoclonal antibody.

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. 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; **AND**

2. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a contraindication to the prescribed drug; **AND**

4. For an osteoporosis-related condition, was evaluated for secondary causes of osteoporosis including complete blood count, vitamin D, ionized calcium, phosphorus, albumin, total protein, creatinine, liver enzymes (specifically alkaline phosphatase), intact parathyroid hormone, thyroid stimulating hormone, 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] of or a contraindication or an intolerance to bisphosphonates,

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

[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.

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 disorder,
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 contraindication or an intolerance 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 requested 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 beneficiary and documented by the prescriber,

c. **One** of the following:

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)

[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.

ii. Is a postmenopausal woman at high risk of fracture2 with a history of therapeutic failure1 of or a contraindication or an intolerance to oral bisphosphonates;

AND

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,2
      ii. Has a documented history of therapeutic failure1 of or a contraindication or an intolerance to the preferred Bone Density Regulators approved or medically accepted for the beneficiary's diagnosis,
      iii. For a parenteral bisphosphonate, has a contraindication or an intolerance to oral bisphosphonates;

AND

9. 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;

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

1. Based on the prescriber's assessment, the beneficiary's condition has stabilized and/or the beneficiary 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;

   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.

B. 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.

C. 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 teriparatide and abaloparatide will be limited to two years cumulative duration of treatment.

3. Prior authorization of romosozumab will be limited to 12 months cumulative duration of treatment.

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BONE DENSITY REGULATORS PRIOR AUTHORIZATION FORM *(form effective 1/5/2026)*

☐New request ☐Renewal request	Total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form:	
Dose/directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

Complete all sections that apply to the beneficiary and this request.

Check all that apply and submit documentation for each item.

INITIAL requests

1. For treatment of an OSTEOPOROSIS-RELATED condition:

☐Has results of a recent bone mineral density test → Document T-score: _____ Date of test: _____

☐Was evaluated for other possible causes of osteoporosis and has results of the following lab tests:

☐CBC	☐Phosphorous	☐Total protein	☐Thyroid stimulating hormone (TSH)
☐Vitamin D	☐Creatinine	☐Urinary calcium excretion	☐Intact parathyroid hormone (PTH)
☐Ionized calcium	☐Albumin	☐Testosterone (if male)	☐Liver enzymes (specifically alkaline phosphatase)

2. For an ANABOLIC AGENT (e.g., Bonsity, Evenity, Forteo, teriparatide):

☐Has a history of fragility fracture

☐Has a history of multiple vertebral fractures

☐Has a history of trial and failure of or a contraindication or an intolerance to bisphosphonates

☐Request will not exceed the cumulative treatment duration recommended in the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

☐**For a PARATHYROID HORMONE ANALOG (e.g., abaloparatide [Tymlos], teriparatide [e.g., Bonsity, Forteo])** – check all that apply to the beneficiary:

☐Paget's disease of the bone	☐Metabolic bone disease other than osteoporosis
☐Bone metastases	☐Hypercalcemic disorder(s)
☐History of skeletal malignancies	☐Unexplained elevations of alkaline phosphatase
☐Open epiphyses	☐Prior external beam or implant radiation therapy involving the skeleton

☐**For EVENITY** – check all that apply to the beneficiary:

- ☐History of myocardial infarction
- ☐History of stroke

☐**For EVENITY or TYMLOS:**

- ☐Has a contraindication or an intolerance to teriparatide

☐**For FORTEO and BONSITY:**

- ☐Has a contraindication or an intolerance to generic teriparatide that would not be expected to occur with the requested drug

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3. For EVISTA (raloxifene):

☐ Check all that apply to the beneficiary:

- ☐ History of venous thromboembolic events (including deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis)
- ☐ History of breast cancer

☐ Has ONE or more risk factors for stroke:

- ☐ History of stroke or TIA ☐ Hypertension ☐ other: _____
- ☐ Atrial fibrillation ☐ Cigarette smoker

☐ If beneficiary has one or more risk factors for stroke, was counseled by the prescriber about the increased risk of death due to stroke

☐ Is a post-menopausal or post-oophorectomy female

☐ Is at high risk for fracture defined by at least ONE of the following:

- ☐ A 10-year probability of hip fracture ≥3% based on the US-adapted WHO algorithm
- ☐ A 10-year probability of major fracture related to osteoporosis ≥20% based on the US-adapted WHO algorithm
- ☐ A history of fragility fracture of the proximal humerus, pelvis, or distal forearm
- ☐ A history of low-trauma spine or hip fracture

☐ Is at high risk for invasive breast cancer defined by at least ONE of the following:

- ☐ Prior biopsy with lobular carcinoma in situ (LCIS) or atypical hyperplasia
- ☐ One or more first-degree relatives with breast cancer
- ☐ A 5-year predicted risk of breast cancer ≥1.66% (based on the modified Gail model)

☐ Has a history of trial and failure of or a contraindication or an intolerance to oral bisphosphonates

4. For DENOSUMAB 120 MG/1.7 ML (i.e., Xgeva and corresponding biosimilars), is being treated for ONE of the following:

☐ Bone metastases from solid tumors

☐ Giant cell tumor of the bone

☐ Hypercalcemia of malignancy

☐ Multiple myeloma

☐ A diagnosis not in the list above that is supported by FDA-approved package labeling, peer-reviewed medical literature, or nationally recognized medical compendia

5. For ALL OTHER Bone Density Regulators:

☐ Is at high risk for fracture defined by at least ONE of the following:

- ☐ A 10-year probability of hip fracture ≥3% based on the US-adapted WHO algorithm
- ☐ A 10-year probability of major fracture related to osteoporosis ≥20% based on the US-adapted WHO algorithm
- ☐ A history of fragility fracture of the proximal humerus, pelvis, or distal forearm
- ☐ A history of low-trauma spine or hip fracture

☐ Has a history of trial and failure of or a contraindication or an intolerance to the preferred Bone Density Regulators *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

☐ **For a PARENTERAL bisphosphonate:**

- ☐ Has a contraindication or an intolerance to oral bisphosphonates

RENEWAL requests

1. For ALL renewal requests:

☐ The beneficiary's condition has stabilized since starting the requested medication

☐ The beneficiary continues to benefit from the requested medication

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: