Gateway Health Plan
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.

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 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**

[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.

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 teriparatide,

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

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[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 with a history of therapeutic failure,[1] intolerance, or contraindication to oral bisphosphonates,

g. For Xgeva (denosumab), **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

[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.

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;

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;

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

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

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EVISTA (raloxifene) PRIOR AUTHORIZATION FORM

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

CLINICAL INFORMATION

Medication requested: ☐Evista 60 mg tablet ☐raloxifene 60 mg tablet		Directions:	
Quantity:	Refills:	Diagnosis:	Dx code (*required*):

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐INITIAL requests:

- ☐Is a post-menopausal or post-oophorectomy female
- ☐Has one or more risk factors for stroke:
  - ☐history of stroke or TIA ☐hypertension ☐other: _____
  - ☐atrial fibrillation ☐cigarette smoker
- ☐Has results of a recent bone mineral density test
- ☐Has a 10-year probability of hip fracture ≥ 3% based on the US-adapted WHO algorithm
- ☐Has a 10-yr probability of major fracture related to osteoporosis ≥ 20% based on the US-adapted WHO algorithm
- ☐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 ☐liver enzymes/LFTs ☐intact parathyroid hormone (PTH)
  - ☐ionized calcium ☐albumin ☐urinary calcium excretion ☐testosterone (if male)
- ☐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)

☐RENEWAL requests:

- ☐Continues to benefit from the requested medication

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Prescriber Signature:	Date:

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EVENITY / FORTEO / TERIPARATIDE / TYMLOS PRIOR AUTHORIZATION FORM *(form effective 1/3/2022)*

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

CLINICAL INFORMATION

Drug requested:	☐Evenity injection ☐Forteo injection	☐teriparatide injection ☐Tymlos injection	☐other: _____
Directions:		Quantity:	Refills:
Diagnosis *(<u>submit documentation</u>)*:		Dx code (*<u>required</u>*):	

INITIAL requests

What is the beneficiary's T-score? T-score: _____ Date of test: _____ *Submit documentation and results of BMD testing.*

Do any of the following apply to the beneficiary? *Check all that apply.*
☐Has a history of fragility fracture ☐Has a history of multiple vertebral fractures
☐Yes ☐No *Submit all supporting documentation.*

Was the beneficiary evaluated for other possible causes of osteoporosis, including the following laboratory tests? *Check all that apply.*

☐CBC	☐albumin	☐thyroid stimulating hormone (TSH)
☐vitamin D	☐total protein	☐urinary calcium excretion
☐ionized calcium	☐creatinine	☐intact parathyroid hormone (PTH)
☐phosphorous	☐liver enzymes/LFTs	☐testosterone (if male)

☐Yes ☐No *Submit results of all requested lab tests.*

<u>Requests for Forteo/teriparatide or Tymlos</u>: Does the beneficiary have a history of any of the following? *Check all that apply.*

☐Paget's disease	☐metabolic bone disorder other than osteoporosis
☐bone metastases	☐prior external beam or implant radiation therapy involving the skeleton
☐skeletal malignancy	☐unexplained elevations in alkaline phosphatase
☐open epiphyses	☐hypercalcemic disorders

☐Yes ☐No *Submit all supporting documentation.*

<u>Requests for Evenity</u>: Does the beneficiary have a history of either of the following: *Check all that apply.*
☐myocardial infarction ☐stroke
☐Yes ☐No *Submit all supporting documentation.*

Does the beneficiary have a history of trial and failure of (i.e., documented continued bone loss or a fragility fracture after 2 or more years of treatment) or contraindication or intolerance to bisphosphonates (e.g., alendronate, risedronate, zoledronic acid, etc.)?
☐Yes ☐No. *Submit documentation of trial and failure, intolerance, or contraindications*

Has the beneficiary been using or previously used an anabolic Bone Density Regulator (Forteo/teriparatide, Tymlos [abaloparatide], Evenity [romosozumab])?
☐Yes – *Submit documentation of start and end dates.* ☐No

<u>Requests for Evenity or Tymlos</u>: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to teriparatide?
☐Yes – *Submit documentation.* ☐No

<u>Requests for Forteo</u>: Does the beneficiary have a contraindication or intolerance to teriparatide that would not be expected to occur with Forteo?
☐Yes – *Submit documentation.* ☐No

RENEWAL requests

Since the requested medication was last approved, did the beneficiary have a follow-up bone mineral density (BMD) test performed?
☐Yes – *Submit documentation of BMD test results.* ☐No

PLEASE <u>FAX</u> COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:

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BONE DENSITY REGULATORS PRIOR AUTHORIZATION FORM

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

CLINICAL INFORMATION

Non-preferred drug requested:		Strength:	Dosage form:
Strength:	Directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

****Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.****

☐INITIAL requests for all agents EXCEPT Xgeva:
- ☐Has results of a recent bone mineral density test
- ☐Has a history of low-trauma spine or hip fracture OR other fragility fracture
- ☐Has a 10-year probability of hip fracture ≥ 3% based on the US-adapted WHO algorithm
- ☐Has a 10-yr probability of major fracture related to osteoporosis ≥ 20% based on the US-adapted WHO algorithm
- ☐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 ☐liver enzymes/LFTs ☐intact parathyroid hormone (PTH)
  - ☐ionized calcium ☐albumin ☐urinary calcium excretion ☐testosterone (if male)
- ☐INITIAL requests for non-preferred ORAL drug in this class:
  - ☐Has a history of trial and failure of or contraindication or intolerance to the preferred oral bisphosphonates
- ☐INITIAL requests for non-preferred INJECTABLE drug in this class:
  - ☐Has a history of trial and failure of or contraindication or intolerance to oral bisphosphonates
  - ☐Has a history of trial and failure of or contraindication or intolerance to the preferred injectable bisphosphonates

☐INITIAL requests for Xgeva:
- ☐Has a diagnosis of giant cell tumor of the bone (NOTE: Giant cell tumor of bone is a benign tumor that typically occurs in young adults between the ages of 20 and 40. It generally occurs at the ends of the body's long bones, most often the lower end of the femur or upper end of the tibia.)
- ☐Does NOT have a diagnosis of giant cell tumor of the bone AND as a history of trial and failure of or contraindication or intolerance to the preferred agents in this class that are FDA-approved or medically accepted for the treatment of the beneficiary's condition

☐RENEWAL requests (all agents):
- ☐Continues to benefit from the requested medication

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: