



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

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## FORTEO (teriparatide) subcutaneous injection Teriparatide subcutaneous injection TYMLOS (abaloparatide) subcutaneous injection

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

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864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). Incomplete forms or forms without the chart notes will be returned.

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### Criteria:

## FORTEO (teriparatide)

### Teriparatide, generic

## TYMLOS (abaloparatide)

- **Criteria for initial therapy:** Forteo (teriparatide) or generic teriparatide or Tymlos (abaloparatide) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Psychiatrist, or Orthopedic Specialist
  2. Individual is 18 years of age or older
  3. Individual with **ONE** of the following:
    - a. Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)] at high risk for fracture (has a history of osteoporotic fracture or has multiple risk factors for fracture) or has failed or is intolerant to other available osteoporosis therapy
    - b. Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture (or has multiple risk factors for fracture) or has failed or is intolerant to other available osteoporosis therapy
    - c. A history of low trauma fragility bone fracture (or has multiple risk factors for fracture) or has failed or is intolerant to other available osteoporosis therapy
    - d. Individual with a FRAX 10-year probability risk of 3% or more for a hip fracture **OR** 20% or more for other bone fracture, as assessed by the World Health Organization Fracture Risk Assessment Tool (FRAX tool) that can be obtained at <https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9>
    - e. **Additional for teriparatide (generic or brand Forteo):**
      - i. Glucocorticoid-induced osteoporosis and is at high risk for fracture associated with current and sustained use of prednisone (or equivalent glucocorticoid) at a daily dose of 5 mg or more and expected to remain on glucocorticoids for 3 months or more
  4. Documented failure, contraindication per FDA label, intolerance to at least **ONE** of the following agents:
    - a. Alendronate
    - b. Ibandronate
    - c. Risedronate
    - d. Zoledronic acid

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5. Documented failure, contraindication per FDA label, intolerance to Prolia (denosumab)
6. **For brand Forteo (teriparatide):** documented failure, contraindication per FDA label, intolerance to generic teriparatide
7. Individual is receiving supplemental calcium **AND** vitamin D with doses adjusted per usual laboratory monitoring
8. No dual therapy, alternating therapy, or sequential therapy with Evenity (romosozumab) or another parathyroid hormone related product
9. No previous use of another parathyroid hormone related product of 2-years duration or previous use of 1-year of Evenity (romosozumab)
10. Individual does not have an underlying hypercalcemic disorder such as primary hyperparathyroidism

#### **Initial approval duration:**

Duration will be determined by combining the number of months of use of any parathyroid hormone analog or Evenity (romosozumab) to allow for an initial duration of 12 months

- **Criteria for continuation of coverage (renewal request):** Forteo (teriparatide) or generic teriparatide or Tymlos (abaloparatide) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, or Orthopedic Specialist
  2. Individual's condition responded while on
    - a. Response is defined as **BOTH** of the following:
      - i. Achieved and maintains increased bone mineral density (e.g., lumbar spine, femoral neck, or total hip) and **ONE** of the following:
        1. Reduced incidence of new vertebral fractures in previously non-deformed vertebrae
        2. Reduced incidence of non-vertebral fractures (e.g., ankle/foot, hip, humerus, pelvis, wrists, ribs, or other sites)
      - ii. No evidence of disease progression
  3. Individual has been adherent with the medication
  4. Individual is receiving supplemental calcium **AND** vitamin D with doses adjusted per usual laboratory monitoring

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5. No dual therapy, alternating therapy, or sequential therapy with Evenity (romosozumab) or another parathyroid hormone related product
6. No previous use of another parathyroid hormone related product of 2-years duration or previous use of 1-year of Evenity (romosozumab)
7. Individual does not have an underlying hypercalcemic disorder such as primary hyperparathyroidism
8. Individual has not developed any significant adverse drug effects that may exclude continued use
  - a. Significant adverse effect such as:
    - i. Osteosarcoma
    - ii. Severe or sustained hypercalcemia
    - iii. Calciphylaxis or worsening of previously stable cutaneous calcification

#### **Renewal duration:**

Duration will be determined by combining the number of months of use of any parathyroid hormone analog or Evenity (romosozumab) to allow for an additional duration of 12 months  
Total lifetime use of more than 24-months of any parathyroid hormone analog will not be approved

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
1. **Off-Label Use of Non-Cancer Medications**
  2. **Off-Label Use of Cancer Medications**
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#### **Description:**

Teriparatide (brand Forteo and generic) is a recombinant form of human parathyroid hormone [rhPTH] which is the primary regulator of bone and mineral metabolism. Teriparatide may be used for treatment of osteoporosis in postmenopausal women, to increase bone mass in men with osteoporosis and for treatment of women and men with osteoporosis associated with sustained systemic glucocorticoid therapy.

Tymlos (abaloparatide) is an analog of human parathyroid hormone related peptide [PTHrP(1-34)] indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture or individuals who have failed or are intolerant to other available osteoporosis therapy.

The use of teriparatide or abaloparatide is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.

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Generally, teriparatide and abaloparatide are given as a 2-year course of treatment. Cumulative use of teriparatide and abaloparatide and parathyroid hormone for more than 2 years during a patient's lifetime is not recommended. There are limited data assessing the risk of osteosarcoma beyond 2 years of use. Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.

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### Definitions:

**Adult:** Age 18 years and older

### T-Scores are reported as standard deviations (SD) World Health Organization (WHO) criteria:

Normal:	T-score within 1 SD
Osteopenia:	T-score of -1 to -2.5 SD
Osteoporosis:	T-score of -2.5 or worse SD
Severe Osteoporosis:	T-score of -2.5 or worse SD with fragility fractures

### Fragility fracture:

- A fracture at the spine, hip, wrist, humerus, rib, or pelvis occurring from a fall from standing height or less, without a major trauma such as motor vehicle accident. Fracture at the skull, cervical spine, hands, or feet are not considered fragility fractures. Stress fractures from repetitive injury are also not considered fragility fractures.

### High risk for fracture is defined as ONE of the following:

- Osteoporotic fracture
- Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
- Failed response (as defined by prescribing provider) to previous osteoporosis therapy
- Intolerant to previous osteoporosis therapy

### Fracture Risk Assessment Tool (FRAX tool):

- The World Health Organization developed a risk assessment tool to assist providers in evaluating osteopenic individuals. The tool uses clinically proven risk factors to determine a 10-year probability of hip fracture and a 10-year probability for a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fractures). Treatment may be considered if the 10-year risk is 3% or more for hip fracture or if the risk for other bone fracture is 20% or more. The tool can be obtained at <https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9>

### Increased risk of osteosarcoma patients with:

- Open epiphyses
- Metabolic bone diseases including Paget's disease
- Bone metastases or history of skeletal malignancies

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- Prior external beam or implant radiation therapy involving the skeleton
- Hereditary disorders predisposing to osteosarcoma.

**Guideline for Pharmacologic Intervention in Postmenopausal Woman and Male 50 years of age or older:**

History of hip or vertebral fracture
T-score $\leq$ -2.5 (DKA) at the femoral neck or spine, after exclusion of secondary causes
T-score between -1 and -2.5 at the femoral neck or spine and a 10-year probability of hip fracture $\geq$ 3% or a 10-year probability of any major osteoporosis-related fracture $\geq$ 20% based on the WHO algorithm

**Available FDA-approved medications for the prevention of osteoporosis in postmenopausal women:**

Drug Class	Medication	Dose
Estrogens	Many	Variable
Biphosphonates	Alendronate	35 mg/week or 5 mg/day
	Risedronate	35 mg/week or 5 mg/day
	Ibandronate	150 mg/month
	Zoledronic acid	5 mg IV once every 2-years
Selective estrogen receptor modulator	Raloxifene	60 mg/day
	Bazedoxifene + conjugated equine estrogen	20 mg + 0.45 mg daily
There is no FDA-approved medications for prevention of osteoporosis in men		

**Oral bisphosphonates should not be used as initial therapy in the following:**

- Patients with esophageal disorders (e.g., achalasia, esophageal strictures, esophageal varices, Barrett's esophagus)
- Inability to follow the dosing requirements (e.g., stay upright for at least 30 to 60 minutes)
- Chronic kidney disease (CKD; estimated glomerular filtration [eGFR] rate <30 mL/min)
- After certain types of bariatric surgery in which surgical anastomoses are present in the gastrointestinal tract (e.g., Roux-en-Y gastric bypass)

**Glucocorticoid Equivalencies:**

Betamethasone	0.75 mg
Cortisone	25 mg
Dexamethasone	0.75 mg
Hydrocortisone	20 mg
Methylprednisolone	4 mg
Prednisone	5 mg
Prednisolone	5 mg

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#### **Resources:**

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Teriparatide product information, revised by Alvogen, Inc. 11-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed March 10, 2022.

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Rosen CJ. Parathyroid hormone/parathyroid hormone-related protein analog for osteoporosis. In: UpToDate, Drezner MK, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated January 28,2022. Accessed March 10, 2022.

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