Pharmacy Medical Necessity Guidelines: Parathyroid Hormone Analogs

Effective: January 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Bonsity (teriparatide), **teriparatide (Forteo)**, **Teriparatide Injection (teriparatide)** are recombinant human parathyroid hormone analogs indicated:

- **Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture**
  To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
- **Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture**
  For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
- **Treatment of postmenopausal women with osteoporosis at high risk for fracture**
  For treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Forteo (teriparatide) reduces the risk of vertebral and nonvertebral fractures

Tymlos (abaloparatide) is a human parathyroid hormone related peptide analog indicated:

- **Treatment of postmenopausal women with osteoporosis at high risk for fracture**
  For treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos (abaloparatide) reduces the risk of vertebral and nonvertebral fractures
- **Treatment to increase bone density in men with osteoporosis at high risk for fracture**
  To increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

COVERAGE GUIDELINES

Tymlos (abaloparatide)

The plan may authorize coverage of **Tymlos (abaloparatide)** for Members when the following criteria are met:

1. Documentation of **one (1)** of the following
   a. T-score less than or equal to -2.5
   b. T-score of less than or equal to -1.0 and greater than -2.5 and the prescriber determines the Member is at high risk for fracture
   c. FRAX score of 10-year risk of major osteoporotic fracture ≥20% or a risk of hip fracture ≥3%
   d. One or more osteoporotic fracture

AND

2. Documentation of **one (1)** of the following
   a. Documentation of an inadequate response to, or inability to tolerate at least one of the traditional osteoporosis treatments (e.g., alendronate, calcitonin, denosumab, ibandronate, raloxifene, risedronate, zoledronic acid)
   b. Contraindication to all traditional osteoporosis treatments (e.g., alendronate, calcitonin, denosumab, ibandronate, raloxifene, risedronate, zoledronic acid)

c. The member is at very high risk for fracture (e.g., T-score of ≤-3.0 in the absence of fragility fracture[s], T-score of ≤-2.5 plus a fragility fracture [fracture from a low energy trauma excludes stress fracture, hand/foot fractures], or multiple fractures)
d. The Member is new to the plan and stable on the requested agent prior to enrollment

Bonsity (teriparatide), teriparatide (Forteo), Teriparatide Injection (teriparatide)
The plan may authorize coverage of **Bonsity, teriparatide (Forteo), or Teriparatide Injection** for Members when the following criteria are met:

Initial Authorization Criteria

1. Documentation of **one (1)** of the following
    a. T-score less than or equal to -2.5
    b. T-score of less than or equal to -1.0 and greater than -2.5 and the prescriber determines the Member is at high risk for fracture
    c. FRAX score of 10-year risk of major osteoporotic fracture ≥20% or a risk of hip fracture ≥3%
    d. One or more osteoporotic fracture

AND

2. Documentation of **one (1)** of the following
    a. Documentation of an inadequate response to, or inability to tolerate at least one of the traditional osteoporosis treatments (e.g., alendronate, calcitonin, denosumab, ibandronate, raloxifene, risedronate, zoledronic acid)
    b. Contraindication to all traditional osteoporosis treatments (e.g., alendronate, calcitonin, denosumab, ibandronate, raloxifene, risedronate, zoledronic acid)
    c. The member is at very high risk for fracture (e.g., T-score of ≤-3.0 in the absence of fragility fracture[s], T-score of ≤-2.5 plus a fragility fracture [fracture from a low energy trauma excludes stress fracture, hand/foot fractures], or multiple fractures)
    d. The Member is new to the plan and stable on the requested agent prior to enrollment

AND

3. If requested use is for postmenopausal women with osteoporosis at high risk for fracture, documentation of an inadequate response to or inability to tolerate Tymlos (abaloparatide)

Reauthorization Criteria

1. Documentation the Member remains at or has returned to having high risk for fracture despite a total of 24 months of use of parathyroid hormone analog therapy.

LIMITATIONS

- Coverage of Tymlos will be limited to 24 months total. Initial approval for teriparatide products will be limited to 24 months and reauthorization will be provided in 12-month intervals.
- The plan does not cover brand name Forteo. Refer to the Pharmacy Medical Necessity Guidelines for Non-covered Pharmacy Products.

CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the Member's pharmacy benefit.

REFERENCES

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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.
1. September 12, 2023: No changes.
2. August 12, 2024: No changes (eff 8/13/24)
3. July 8, 2025: Effective 8/1/25, updated coverage criteria to add patients at very high risk for fracture. Added criterion for contraindications to prerequisite trial.
4. December, 9, 2025: Effective 1/1/26, added Bonsity to the MNG. Clarified product names available for teriparatide injection throughout the MNG and updated Limitations to indicate that the brand name Forteo is not covered by the plan. Added recertification criteria for teriparatide products for use beyond 2 years of therapy based on recommended treatment duration per package insert. Updated Limitations to clarify that coverage for Tymlos will be limited to 24 months of therapy total and initial approval for teriparatide products will be limited to 24 months and reauthorization will be provided in 12-month intervals.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.