Pharmacy Medical Necessity Guidelines: Forteo® (teriparatide)

Effective: September 18, 2018

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<th>Prior Authorization Required</th>
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Pharmacy (RX) or Medical (MED) Benefit

Department to Review: RXUM

Fax Numbers:

RXUM: 617.673.0988

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Forteo (teriparatide) is recombinant human parathyroid hormone analog (1-34), [rhPTH(1-34)] 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, Forteo (teriparatide) reduces the risk of vertebral and nonvertebral fractures

- 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

COVERAGE GUIDELINES

Increase of Bone Mass in Men with Primary or Hypogonadal Osteoporosis at High Risk for Fracture and Treatment of Men and Women with Glucocorticoid-Induced Osteoporosis at High Risk for Fracture

The plan may authorize coverage of Forteo (teriparatide) for Members when the following criteria are met:

1. Documentation of one of the following:
   a. The requesting physician has documented that the Member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan
   b. The requesting physician has documented that the Member has had one or more osteoporotic fractures

2. Documentation of one of the following:
   a. 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. The Member is new to the plan and was stabilized on Forteo (teriparatide) prior to enrollment
Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture

The plan may authorize coverage of Forteo (teriparatide) for Members when the following criteria are met:

1. Documentation of one of the following:
   a. The requesting physician has documented that the Member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan
   b. The requesting physician has documented that the Member has had one or more osteoporotic fractures

AND

2. Documentation of one of the following:
   a. Documentation of an inadequate response to, or inability to tolerate BOTH of the following:
      • At least one of the traditional osteoporosis treatments [e.g., alendronate (Fosamax), calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)] AND
      • Tymlos (abaloparatide)
   b. The Member is new to the plan and was stabilized on Forteo (teriparatide) prior to enrollment

LIMITATIONS

1. Coverage of human parathyroid hormone analog therapy will be limited to 24 months total for any combination of agents (Forteo and Tymlos).
2. Coverage of Forteo will not be approved when used in combination with any of the osteoporosis agents named above.

CODES

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

REFERENCES


**APPROVAL HISTORY**

April 8, 2003: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- May 10, 2005: Delete "with a T-score of less than -2.5" from criteria #1. Delete "with a T-score of less than -2.0" from criteria #3.
- April 11, 2006: Changed criteria #1 from “the requesting physician has documented that the Member has osteoporosis and is at high risk for fracture” to “the requesting physician has documented that the Member has osteoporosis as evidenced via bone density scan and is at high risk for fracture.” Changed criteria #3 from “the requesting physician has documented that the male Member has hypogonadism and is at high risk for fracture” to “the requesting physician has documented that the male Member has hypogonadism, osteopenia as evidenced by bone density scan, and is at high risk for fracture.” Added Boniva to criteria #4.
- March 13, 2007: No changes
- March 4, 2008: No changes
- January 13, 2009: Added Evista (raloxifene) and Reclast (zoledronic acid) to criteria #4. Added “(T score less than or equal to -2.0)” to criteria #1. Deleted criteria #3: “the requesting physician has documented that the male Member has hypogonadism, osteopenia as evidenced by bone density scan, and is at high risk for fracture.”
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- January 12, 2010: Changed criterion #1 from “the requesting physician has documented that the Member has osteoporosis as evidenced via bone density scan (T score less than or equal to -2.0) and is at high risk for fracture” to "the requesting physician has documented that the Member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan.”
- November 9, 2010: Added denosumab (Prolia™) to list of prerequisite osteoporosis treatments
- November 15, 2011: No changes.
- November 6, 2012: No changes.
- October 15, 2013: No changes.
- October 7, 2014: No changes.
- September 16, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template
- August 9, 2016: Added approval language for members new to the plan and stabilized on Forteo (teriparatide) prior to enrollment. Effective January 1, 2017, moved Tufts Health Together to
Commercial Medical Necessity Guidelines. Changes for Tufts Health Together include addition of limitation #2 and specific T score requirement.

- **April 11, 2017:** Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- **September 12, 2017:** Updated the limitation to clarify that the 24 month authorization duration applies to any combination of human parathyroid hormone analog therapy. Effective 1/1/18, prerequisite trial requirement with Tymlos (abaloparatide) added for the treatment of postmenopausal women with osteoporosis at high risk for fracture.
- **September 18, 2018:** No changes

### 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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.