Pharmacy Medical Necessity Guidelines: Parathyroid Hormone Analogs

Effective: January 1, 2021

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Teriparatide Injection is recombinant human parathyroid hormone analog 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

COVERAGE GUIDELINES

Tymlos (abaloparatide)

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

1. Documentation of one of the following
    a. 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
    b. T-score less than or equal to -2.5
    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 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. The Member is new to the plan and stable on the requested agent prior to enrollment

Teriparatide Injection

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

1. Documentation of one of the following
    a. 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
    b. T-score less than or equal to -2.5
    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 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. 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)

LIMITATIONS

- Coverage of parathyroid hormone analog therapy will be limited to 24 months total for any combination of agents.
- Coverage of parathyroid hormone analogs will not be approved when used in combination with any of the osteoporosis agents named above.
- The plan dose not cover the following medications on all Commercial and Medicaid formularies: Forteo (teriparatide).

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

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

Subsequent endorsement date(s) and changes made:

1. 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.
2. 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.
3. March 13, 2007: No changes
4. March 4, 2008: No changes
5. 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, osetopenia as evidenced by bone density scan, and is at high risk for fracture."
6. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
7. 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."
8. November 9, 2010: Added denosumab (Prolia™) to list of prerequisite osteoporosis treatments
9. November 15, 2011: No changes.
10. November 6, 2012: No changes.
11. October 15, 2013: No changes.
12. October 7, 2014: No changes.
13. September 16, 2015: No changes.
14. January 1, 2016: Administrative change to rebranded template
15. 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.
16. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
17. 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.
18. September 18, 2018: No changes.
19. March 12, 2019: No changes.
20. August 13, 2019: Effective September 10, 2019, expanded criteria for establishing fracture risk.
21. October 13, 2020: Effective January 1, 2021, changed title of Medical Necessity Guideline from Forteo (teriparatide) to Parathyroid Hormone Analogs and added Tymlos (abaloparatide) with no changes to existing coverage criteria. Moved Forteo (teriparatide) to non-covered status and added Teriparatide Injection to the Medical Necessity Guideline.

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.