Pharmacy Medical Necessity Guidelines: Tymlos™ (abaloparatide)

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

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

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos (abaloparatide) and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

COVERAGE GUIDELINES

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. The Member has had an inadequate response to, or is unable to tolerate therapy with 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 Tymlos (abaloparatide) prior to enrollment

LIMITATIONS

- Coverage of human parathyroid hormone analog therapy will be limited to 24 months total for any combination of agents (Forteo and Tymlos).
- Coverage of Tymlos (abaloparatide) 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

1. American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis -2016.

Endocr Pract. 2016; 22(Suppl 4): 1-42. URL: https://www.aace.com/publications/guidelines Accessed 2017 May 15.
2. Cosman F, Miller PD, Williams GC, et al. Eighteen months of treatment with subcutaneous abaloparatide followed by 6 months of treatment with alendronate in postmenopausal women with osteoporosis: Results of the ACTIVExtend Trial. *Mayo Clin Proc*. 2017; 92(2):200-10.
3. Jeremiah Mr, Unwin BK, Greenwald MH and Casiano VE. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015; 92(4):261-8. URL: http://www.aafp.org/afp/2015/0815/p261.html Accessed 2017 May 19.
4. Miller PD, Hattersley G, Bente JR, et al. Effect of abaloparatide vs. placebo on new vertebral fractures in postmenopausal women with osteoporosis: A randomized clinical trial. *JAMA*. 2016; 316(7):722-33.
5. National Institute for Health and Care Excellence. Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. 2011 January. URL: https://www.nice.org.uk/guidance/ta161/chapter/1-guidance **.** Accessed 2017 May 15.
6. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. 2014. URL: https://link.springer.com/article/10.1007%2Fs00198-014-2794-2. Accessed 2017 May 15.
7. Tymlos (abaloparatide) [prescribing information]. Waltham, MA: Radius Health, Inc. 2018 October.

APPROVAL HISTORY

September 12, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. September 18, 2018: No changes.
2. March 12, 2019: No changes.
3. August 13, 2019: Effective September 10, 2019, expanded criteria for establishing fracture risk.
4. October 13, 2020: Effective January 1, 2021, retire Medical Necessity Guideline. Coverage criteria for Tymlos (abaloparatide) will be moved to Parathyroid Hormone Analogs Medical Necessity Guideline with 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. 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.

Provider Services