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 Subject: Forteo (teriparatide)
 Effective Date: November 15, 2011

Clinical Documentation and Prior Authorization Required	√	Type of Review — Case Management	
Not Covered		Type of Review — Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Administrative Process (Internal Use Only)	LPN

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

Overview

FDA-APPROVED INDICATIONS

Forteo (teriparatide) is 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, Forteo (teriparatide) reduces the risk of vertebral and nonvertebral fractures.

Forteo (teriparatide) is indicated 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.

Forteo (teriparatide) is indicated 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.

Pharmacy Coverage Guidelines

Tufts Health Plan may authorize coverage of Forteo (teriparatide) for Members when either criteria #1 or #2 is met **AND** criterion #3 is met:

1. 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.

OR

2. The requesting physician has documented that the Member has had one or more osteoporotic fractures.

AND

3. The Member has had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments [alendronate (Fosamax®), calcitonin (Miacalcin®), denosumab (Prolia™), ibandronate (Boniva®), raloxifene (Evista®), risedronate (Actonel®), zoledronic acid (Reclast®)].

Limitations

1. Coverage of Forteo is limited to 24 months.
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

1. Forteo product information. Eli Lilly and Company. December 2002.
2. Burnham TH, Novak K, eds. Drug Facts and Comparisons. January 2003 (updated monthly).
3. McEvoy GK (ed). American Hospital Formulary Service/AHFS Drug Information 2003. Bethesda: The American Society of Health-System Pharmacists, Inc. 2002.
4. Neer RM, Arnaud CD, Zanchetta FR, et al. Effect of parathyroid (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *N Engl J Med.* 2001;334(19):1434-41.
5. Orwoll ES, Scheele WH, Paul S, et al. The effect of teriparatide [human parathyroid hormone (1-34)] therapy on bone density in men. *J Bone Miner Res.* 2003;8(1):9-17.
6. J.A. Kanis, World Health Organization Fracture Risk Assessment Tool. <http://www.shef.ac.uk/FRAX/>
7. Forteo (teriparatide [rDNA origin] injection) [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2010.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee on April 8, 2003.

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, osteopenia as evidenced by bone density scan, and is at high risk for fracture."

6. January 1, 2010:
 - Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts 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.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health 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). Tufts Health 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 Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member’s benefit document. Check the applicable formulary in the Pharmacy section of our Web site at <http://www.tuftshealthplan.com/providers> to determine if the drug requires you to get prior authorization. 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 Medicare Preferred, please refer to Tufts 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.