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Subject: Oral Bisphosphonates
Effective Date: January 10, 2012

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 Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

Overview

FDA-APPROVED INDICATIONS

Actonel[®] is indicated for the

- Treatment and prevention of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, Actonel reduces the incidence of vertebral fractures and a composite endpoint of nonvertebral osteoporosis-related fractures.
- Treatment to increase bone mass in men with osteoporosis.
- Treatment and prevention of glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoid treatment (daily dosage of ≥ 7.5 mg prednisone or equivalent) for chronic diseases. Patients treated with glucocorticoids should receive adequate amounts of calcium and vitamin D.
- Treatment of Paget's disease of bone in men and women.

Boniva[®] is indicated for the

- Treatment and prevention of osteoporosis in postmenopausal women. Boniva increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

Fosamax[®] is indicated for the

- Treatment and prevention of osteoporosis in postmenopausal women. For the treatment of osteoporosis, Fosamax increases bone mass and reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures). Osteoporosis may be confirmed by the finding of low bone mass (for example, at least 2 standard deviations below the premenopausal mean) or by the presence or history of osteoporotic fracture. For the prevention of osteoporosis, Fosamax may be considered in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and to reduce the risk of future fracture. Bone loss is particularly rapid in postmenopausal women younger than age 60. Risk factors often associated with the development of postmenopausal osteoporosis include early menopause; moderately low bone mass (for example, at least 1 standard deviation below the mean for healthy young adult women); thin body build; Caucasian or Asian race; and family history of osteoporosis. The presence of such risk factors may be important when considering the use of Fosamax for prevention of osteoporosis.
- Treatment to increase bone mass in men with osteoporosis.

- Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who have low bone mineral density. Patients treated with glucocorticoids should receive adequate amounts of calcium and vitamin D.
- Treatment of Paget's disease of bone in men and women. Treatment is indicated in patients with Paget's disease of bone having alkaline phosphatase at least two times the upper limit of normal, or those who are symptomatic, or those at risk for future complications from their disease.

Pharmacy Coverage Guidelines

Note: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Commercial Massachusetts Formulary	Tufts Health Plan Generic Focused Formulary	Tufts Health Plan Commercial R.I. Formulary
Step-1			
alendronate	Covered	Covered	Covered
Fosamax oral solution			
Step-2			
Actonel	Requires prior use of a drug on Step-1	Requires prior use of a drug on Step-1	Requires prior use of a drug on Step-1
Actonel with Calcium			
Boniva tablet			
Not Covered			
Atelvia	Tufts Health Plan may cover drugs if the following criteria are met:		
Fosamax tablet	A formulary exception request is submitted and approved by Tufts Health Plan. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs.		
Fosamax Plus D	<p style="text-align: center;">AND</p> The Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of an adequate trial or intolerance of two formulary oral bisphosphonate alternatives.		

Automated Step Therapy Coverage Criteria

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: Tufts Health Plan may cover Step 2 medications if the following criteria are met:

- The member has had a 30-day trial of a Step-1 or Step-2 oral bisphosphonate within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

Step 2: Tufts Health Plan may cover Step 2 medications if the following criteria are met

- The Member has had a previous trial of Step-1 or Step-2 oral bisphosphonate as evidenced by physician documented use within the last 2 years, excluding the use of samples.

Limitations

1. Medications on Step-2 or Step-3 are not covered unless the above step therapy criteria are met.

Codes

None.

References

1. Actonel[®] (risedronate sodium) [package insert]. Cincinnati, OH: Procter & Gamble Pharmaceuticals; April 2008.
2. Boniva[®] (ibandronate sodium) [package insert]. Nutley, NJ: Roche Pharmaceuticals; November 2008.
3. Fosamax[®] (alendronate sodium) [package insert]. Whitehouse Station, NJ: Merck & Co.; February 2008.
4. Atelvia[®] (risedronate sodium) [package insert]. North Norwich, NY: Norwich Pharmaceuticals; October 2010.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee on March 10, 2009.

Subsequent Endorsement Date(s) and Changes Made:

1. September 8, 2009:
 - Added Step Therapy Program to Commercial and Rhode Island formularies.
2. January 1, 2010:
 - Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
3. September 14, 2010: No changes.
4. January 11, 2011:
 - Added Atelvia to Step-3 (Non-covered) of the Step Therapy Program.
5. September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
6. January 10, 2012: Removed the "Step-3" wording as these medications are not covered and are not part of the automated step therapy as they require an exception request.

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 Website at www.tuftshealthplan.com 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 Step Therapy 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.