Pharmacy Medical Necessity Guidelines: Bisphosphonate Medications (alendronate with vitamin D, ibandronate, risedronate)

Effective: October 1, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	PO: RX/ IV:MED	Department to Review	RXUM /MM

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
MM: 888.415.9055

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

OVERVIEW

FDA-APPROVED INDICATIONS

Oral bisphosphonates are indicated for:

- Treatment of postmenopausal osteoporosis (OP) (alendronate, ibandronate, risedronate);
- Prevention of postmenopausal osteoporosis (alendronate, ibandronate, risedronate);
- Treatment of osteoporosis in males (alendronate, risedronate);
- Treatment of Paget's disease of the bone (alendronate, risedronate);
- Treatment and prevention of glucocorticoid-induced osteoporosis (alendronate, risedronate)

Please refer to the Zoledronic Acid Medical Necessity Guideline for requests for zoledronic acid products.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred bisphosphonate product for Members when one of the following criterions is met and limitations do not apply:

Ibandronate, Risedronate:

1. The request is for Paget's disease, hypercalcemia of malignancy, bone metastases, osteolytic/bone disease, or potential skeletal-related events secondary to a diagnosis of cancer or associated with cancer treatments

OR

2. The Member tried and failed therapy with alendronate, or there is clinical justification to avoid therapy with alendronate

Fosamax + D (alendronate/cholecalciferol):

1. Member has an intolerance to or compliance issue with a trial of generic alendronate and vitamin D taken individually and concurrently

LIMITATIONS

1. Combination products require the Member to utilize the bisphosphonate and the dietary supplement, such as vitamin D or calcium, separately.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria.
3. Quantity limits apply as follows:

Generic name	Strength (mg)	Treatment and prevention of post-menopausal OP	Male OP	Glucocorticoid-induced OP	Paget's disease
		Recommended Monthly Dosing			
Alendronate	5	#30 (prevention)		#30	
	10	#30	#30	#30 (postmenopausal women not receiving estrogen)	
	35	#4 (prevention)			
	40				#30/mon x 6 mon
	70	#4 (treatment)	#4		
Alendronate/ cholecalciferol	70 mg/ 2800 IU	#4 (treatment)	#4		
	70 mg/ 5600 IU	#4 (treatment)	#4		
Ibandronate	2.5	#30			
	150	#1			
	3/3ml	#3ml q 3mon			
Risedronate	5	#30		#30	
	30				#30/mon x 2 mon
	35 (IR)	#4	#4		
	35 (DR)	#4 (treatment)			
	75	#2			
	150	#1			

CODES

None

REFERENCES

1. Management of Osteoporosis in Postmenopausal Women: 2010 Position Statement of The North American Menopause Society. *Menopause*. 2010; 17(1):25-54
2. Fosamax® (alendronate) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; August 2019.
3. Fosamax Plus D (alendronate sodium/cholecalciferol) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; August 2019.
4. National Osteoporosis Foundation (NOF), "Clinician's Guide to Prevention and Treatment of Osteoporosis," Washington, DC, 2014. Available at https://my.nof.org/file/bonesource/Clinicians-Guide.pdf
5. Boniva® (ibandronate sodium) [prescribing information]. San Francisco, CA: Genentech; December 2016.
6. Actonel® (risedronate sodium) [prescribing information]. Madison, NJ: Allergan USA, Inc; November 2019.

APPROVAL HISTORY

July 17, 2008: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. October 14, 2014: No changes
2. September 16, 2015: No changes
3. January 1, 2016: Administrative change to rebranded template.
4. September 13, 2016: Removed Skelid® from the policy due to product discontinuation.
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
6. November 14, 2017: No changes.
7. November 13, 2018: Administrative changes made to template.
8. August 13, 2019: No changes.

9. July 14, 2020: Effective October 1, 2020, updated criteria for alendronate/cholecalciferol.

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