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

Effective: September 15, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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 (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)

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:

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 had an inadequate response, adverse reaction, or contraindication to alendronate, or there is clinical justification to avoid therapy with alendronate

Fosamax + D (alendronate/vitamin D):

1. The Member has compliance issues with a trial of both 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.

CODES

None

REFERENCES

1. Actonel® (risedronate sodium) [prescribing information]. Madison, NJ: Allergan USA, Inc; October 2023 .
2. Boniva® (ibandronate sodium) [prescribing information]. San Francisco, CA: Genentech; October 2020.
1. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25:2359-2381. Fosamax® (alendronate) [prescribing information]. Jersey City, NJ: Organon & Co.; June 2021.
2. Fosamax Plus D (alendronate sodium/cholecalciferol) [prescribing information]. Jersey City, NJ: Organon & Co; April 2024 .
3. North American Menopause Society. Management of osteoporosis in postmenopausal women: 2021 position statement of The North American Menopause Society. *Menopause*. 2021; 28(9):973-997

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, updated previous trial language for risedronate. Updated criteria for Fosamax+D to require compliance issues with both generic alendronate and vitamin D.
2. September 10, 2024: Administrative change to fax number
3. September 9, 2025: No changes
4. September 15, 2026: 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