Clinical Policy: Alendronate (Binosto, Fosamax Plus D)

Reference Number: CP.PMN.88
Effective Date: 03.01.18
Last Review Date: 02.25
Line of Business: Commercial, HIM*, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Alendronate sodium effervescent tablets (Binosto®) and alendronate/cholecalciferol (Fosamax Plus D®) are oral bisphosphonates.

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***For Health Insurance Marketplace (HIM),** Binosto is non-formulary and should not be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Binosto, Fosamax Plus D, and alendronate oral solution are indicated for:

- Treatment of osteoporosis in postmenopausal women (PMO).
- Treatment to increase bone mass in men with osteoporosis.

Limitation(s) of use:

- Binosto, Fosamax Plus D, and alendronate oral solution: Optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3 to 5 years of use.
- Fosamax Plus D alone should not be used to treat vitamin D deficiency.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Binosto, Fosamax Plus D, and alendronate oral solution are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis (must meet all)**:**

1. Diagnosis of PMO or male osteoporosis;
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. Failure of a 12-month trial of formulary/preferred drug list (PDL) generic alendronate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed one of the folowing (a, b, or c):
   a. Binosto: 70 mg (1 tablet) per week;
   b. Fosamax Plus D: 70 mg/5600 IU (1 tablet) per week;
   c. Alendronate oral solution: 70 mg (1 bottle) per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Osteoporosis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. Binosto: 70 mg (1 tablet) per week;
   b. Fosamax Plus D: 70 mg/5600 IU (1 tablet) per week;
   c. Alendronate oral solution: 70 mg (1 bottle) per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list
PMO: postmenopausal osteoporosis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	• Treatment: PMO, male osteoporosis 10 mg PO QD or 70 mg PO once weekly • Prevention: PMO 5 mg PO QD or 35 mg PO once weekly	40 mg/day 70 mg/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia; inability to stand/sit upright for at least 30 minutes; hypocalcemia; hypersensitivity; increased risk of aspiration (Binosto and alendronate oral solution only)
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Alendronate effervescent (Binosto), alendronate oral solution	Treatment: PMO, male osteoporosis	70 mg PO once weekly	70 mg/week
Alendronate/ cholecalciferol (Fosamax Plus D)		70 mg alendronate /2800 IU vitamin D3 or 70 mg alendronate /5600 IU vitamin D3 PO once weekly	70 mg / 5600 IU/ week

VI. Product Availability

Drug Name	Availability
Alendronate effervescent (Binosto)	Effervescent tablet: 70 mg
Alendronate/cholecalciferol (Fosamax Plus D)	Tablets: 70 mg/2800 IU, 70 mg/5600 IU
Alendronate	Oral Solution: 70 mg/75 mL

VII. References

1. Fosamax Plus D Prescribing Information. Jersey City, NJ: Organon LLC; August 2021. Available at: https://www.organon.com/product/usa/pi_circulars/f/fosamax/fosamax_plus_d_pi.pdf. Accessed October 22, 2024.
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11. Qaseem A, Hicks LA, Etxeandia-Ikobaltzeta I, et al. Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians (Version 1, Update Alert). Ann Intern Med. 2024 Jun; 177(6): eL230113.

Male Osteoporosis

12. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guidelines. *J Clin Endocrinol Metab* 2012;97(6):1802-1822.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review: added Medicaid line of business; age or closed epiphyses added; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.26.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.13.21	02.22
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less.	04.27.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.01.22	02.23
1Q 2024 annual review: no significant changes; clarified failure of a "generic" alendronate is preferred; references reviewed and updated.	10.19.23	02.24
1Q 2025 annual review: added alendronate oral solution to policy; clarified redirection to generic alendronate should be a formulary/preferred drug list (PDL) product; references reviewed and updated.	10.22.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.