Clinical Policy: Alendronate (Binosto, Fosamax plus D)

Reference Number: CP.PMN.88
Effective Date: 03.01.18
Last Review Date:
Line of Business: Commercial, HIM* 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 requiring prior authorization.

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

FDA Approved Indication(s)

Binosto and Fosamax plus D are indicated:

- For the treatment of osteoporosis in postmenopausal women.
- For treatment to increase bone mass in men with osteoporosis.

Limitation(s) of use: The optimal duration of use for bisphosphonates has not been determined. The safety and effectiveness of bisphosphonates for the treatment of osteoporosis are based on clinical data of one to four years duration. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.

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 and Fosamax plus D are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of osteoporosis;
2. Age ≥ 18 years;
3. Failure of preferred alendronate tablets at up to maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed:
   Binosto: 70 mg/week (1 tablet/week);
   Fosamax plus D: 70 mg /5600 IU/week (1 tablet/week).

Approval duration:

HIM – Fosamax plus D: 12 months *(Refer to HIM.PA.103 for Binosto)*

Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Binosto 70 mg/week (1 tablet);
   b. Fosamax plus D 70 mg/5600 IU weekly (1 tablet).

Approval duration:
HIM – Fosamax plus D: 12 months *(Refer to HIM.PA.103 for Binosto)*
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace.

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.PHAR.21 for health insurance marketplace.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GIO: glucocorticoid-induced osteoporosis
MO: male osteoporosis
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	Dosing Regimen	Dose Limit/ Maximum Dose
Alendronate (Fosamax®)	PMO/Male Osteoporosis treatment: 10 mg PO QD or 70 mg PO once weekly PMO Prevention: 5 mg PO QD or 35 mg PO once weekly Paget's disease: 40 mg PO QD for 6 months	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.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Alendronate effervescent (Binosto)	PMO, MO	70 mg PO once weekly	70 mg/week
Alendronate and Cholecalciferol (Fosamax Plus D)	PMO, MO	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	Availability
Alendronate effervescent (Binosto)	Effervescent Tablet: 70 mg
Alendronate and Cholecalciferol (Fosamax Plus D)	Tablet: 70 mg/2800 IU, 70 mg/5600 IU

VII. References

1. Fosamax Plus D Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc; March 2016. Available at: https://www.merck.com/product/usa/pi_circulars/f/fosamax/fosamax_pi.pdf. Accessed December 1, 2017.
2. Binosto Prescribing Information. San Antonio, TX: Mission Pharmacal Company; July 2016. Available at: https://www.binosto.com. Accessed December 1, 2017.
3. National Osteoporosis Foundation-The Clinician`s Guide to Prevention and Treatment of Osteoporosis. Available at: https://cdn.nof.org/wp-content/uploads/2016/01/995.pdf Accessed December 1, 2017.
4. The North American Menopause Society. Management of postmenopausal osteoporosis: 2010 position statement of the North American Menopause Society. Menopause 2010; 17(1):22-54.

5. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract 2010; 16 (Suppl 3):1-37.
6. Grossman JM, Gordon R, Ranganath VK, et al. American College of Rheumatology 2010 recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Care Res 2010; 62 (11):1515-1526.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created -Split from HIM.PA.51 and CP.CPA.212 – oral bisphosphonates. -Combined policy for marketplace and commercial lines of business -No significant changes from previous corporate approved policy. -References reviewed and updated.	12.01.17	02.18

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.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.