Clinical Policy Title:	alendronate, alendronate/cholecalciferol
Policy Number:	RxA.38
Drug(s) Applied:	Binosto®, Fosamax Plus D®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Alendronate is an oral bisphosphonate. These drug products 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 the use of bisphosphonates has not been determined. The safety and effectiveness of bisphosphonates for the treatment of osteoporosis are based on clinical data of 1 to 4 years duration. All patients on bisphosphonate therapy should be 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
alendronate effervescent (Binosto®)	PMO, MO	70 mg PO once weekly	70 mg/week
alendronate/ 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 per week

Dosage Forms

- alendronate effervescent (Binosto®) - Effervescent tablet: 70 mg
- alendronate/cholecalciferol (Fosamax Plus D®) -Tablet: 70 mg/2800 IU, 70 mg/5600 IU

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of osteoporosis;
2. Age 18 years of age or older;

3. Medical justification supports inability to use preferred alendronate tablets at maximally indicated doses (e.g., contraindications to the excipients of all brand and generic products);
4. Dose does not exceed 1 tablet per week (Binosto® - 70 mg per week; Fosamax Plus D® - 70 mg/5600 IU per week).

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tablet per week (Binosto® - 70 mg per week; Fosamax Plus D® - 70 mg/5600 IU per week).

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GIO: Glucocorticoid-induced osteoporosis
MO: Male osteoporosis
PMO: Postmenopausal osteoporosis
PO: By mouth

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	PMO/male osteoporosis treatment: 10 mg PO once daily or 70 mg PO once weekly PMO prevention: 5 mg PO once daily or 35 mg PO once weekly Paget's disease: 40 mg PO once daily for 6 months	40 mg/day or 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® only).
- Boxed warning(s):
  - None reported

Appendix D: General Information

None

References

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2. The North American Menopause Society. Management of postmenopausal osteoporosis: 2010 position statement of the North American Menopause Society. Menopause 2010; 17(1):22-54.
3. 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.
4. 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.
5. American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. Ann intern Med. 2017; 166: 818-839.
6. Camacho PM, Petak SM, Brinkley N et al. AACE/ACE Guidelines- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol 22 (suppl 4) September 2016.
7. Alendronate. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, February 17. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed January 26, 2021.
8. Binosto Prescribing Information. Herndon, VA: Ascend Therapeutics; September, 2019. Available at: https://www.binosto.com/sites/default/files/BIN_11567_I0101R0919_Binosto%20PI_FNL2.pdf. Accessed April 28, 2020.
9. Fosamax Plus D Prescribing Information. Whitehouse Station, NJ. Merck & Co., Inc.; August, 2019. Available at: https://www.merck.com/product/usa/pi_circulars/f/fosamax/fosamax_plus_d_pi.pdf. Accessed January 26, 2021.
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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy reviewed & updated.	04/28/2020	05/21/2020
Policy was reviewed: 1. Line of Business Policy Applies to was update to all lines of business. 2. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested	01/26/2021	03/09/2021

therapeutic alternatives based on clinical guidance...." 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Initial and Continued Approval criteria: approval duration was updated from Length of Benefit to 12 months 5. References were updated.		