Clinical Policy: Ibandronate Oral (Boniva)

Reference Number: CP.PMN.96
Effective Date: 03.01.18
Last Review Date: 02.24
Line of Business: Medicaid

Revision Log

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

Description

Ibandronate (Boniva®) is an oral bisphosphonate.

FDA Approved indication(s)

Boniva is indicated for the treatment and prevention of post-menopausal osteoporosis (PMO). Boniva increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

Limitation(s) of use: 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.

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 oral ibandronate is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Request is for treatment or prevention of PMO;
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. Failure of a 12-month trial of generic alendronate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for brand Boniva, member must use generic ibandronate, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed both of the following (a and b):
   a. 150 mg per month;
   b. 1 tablet per month.

Approval duration: 12 months

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.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.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.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 brand Boniva, member must use generic ibandronate, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, dose does not exceed both of the following (a and b):
   a. 150 mg per month;
   b. 1 tablet per month.

Approval duration: 12 months

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.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.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.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 policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMD: bone mineral density
FDA: Food and Drug Administration
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 for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	Treatment: PMO 10 mg PO QD or 70 mg PO once weekly Prevention: PMO 5mg PO QD or 35 mg PO once weekly	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 60 minutes, hypocalcemia, hypersensitivity
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PMO	150 mg PO once monthly on the same day each month	150 mg/month

VI. Product Availability

Tablet: 150 mg

VII. References

1. Ibandronate Sodium Prescribing Information. Morristown, NJ: Alvogen, Inc. April 2022. Available at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=acbc54fc-4248-416f-849c-2cd3bed0a843. Accessed October 19, 2023.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2023. URL: www.clinicalkeys.com/pharmacology.

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3. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an endocrine society guideline update. *J Clin Endocrinol Metab*; March 2020, 105(3): 587-594.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*; 2019, 104: 1595–1622.

5. Camacho PM, Petak SM, Brinkley N et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. *Endocr Pract.* 2020;26(1):1-46.
6. LeBogg MS, Greenspan SL, Insongna KL, et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporo Int.* 2022 Oct;33(10):2049-2102. doi: 10.1007/s00198-021-05900-y. Epub 2022 Apr 28. Erratum in: *Osteoporos Int.* 2022 Jul 28.
7. Siris ES, Adler R, Bilezikian J, et al. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. *Osteoporos Int.* 2014; 25:1439–1443. DOI 10.1007/s00198-014-2655-z.
8. Hodsman AB, Bauder DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. *Endocr Rev*. 2005 Aug;26(5):688-703. Epub 2005 Mar 15.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review: age or closed epiphyses added; alendronate trial 12 month duration added; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.26.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.14.21	02.22
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: added criteria "for brand name Boniva request, member must use generic ibandronate"; clarified failure of "generic" alendronate is preferred; updated contraindication in Appendix C per PI; references reviewed and updated.	10.19.23	02.24

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.

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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.

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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.

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