

Clinical Policy: Ibandronate Injection (Boniva)

Reference Number: CP.PHAR.189

Effective Date: 11.15.17

Last Review Date: 02.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Ibandronate injection (Boniva®) is a bisphosphonate.

FDA Approved Indication(s)

Boniva is indicated for the treatment of osteoporosis in postmenopausal women (PMO). In postmenopausal women with osteoporosis, Boniva increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

Limitation(s) of use: The safety and effectiveness of ibandronate sodium injection for the treatment of osteoporosis are based on clinical data of one year duration. The optimal duration of use has not been determined. 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 ibandronate injection is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Osteoporosis** (must meet all):

1. Diagnosis of PMO;
2. Age $\geq$ 18 years or documentation of closed epiphyses on x-ray;
3. Failure of a 12-month trial of an oral bisphosphonate* (*see Appendix B; generic alendronate is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required.*
4. Member must use generic ibandronate injection, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed both of the following (a and b):
 - a. 3 mg every 3 months;
 - b. 1 syringe every 3 months.

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or to the member’s renewal date, whichever is longer

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. Member must use generic ibandronate injection, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
 - a. 3 mg every 3 months;
 - b. 1 syringe every 3 months.

Approval duration:

Medicaid/HIM – 12 months

Commercial – 6 months or to the member’s renewal date, whichever is longer

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

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<i>Oral bisphosphonates</i>		
alendronate (Fosamax [®])	10 mg PO QD or 70 mg PO once weekly	40 mg/day 70 mg/week
Fosamax [®] Plus D (alendronate / cholecalciferol)	70 mg alendronate /2800 IU vitamin D3 or 70 mg alendronate /5600 IU vitamin D3 PO once weekly	70 mg / 5600 IU/ week
risedronate (Actonel [®] , Atelvia [®])	<u>Actonel:</u> 5 mg PO QD or 35 mg PO once weekly or 75 mg PO QD taken on two consecutive days each month or 150 mg PO once monthly <u>Atelvia:</u> 35 mg PO once weekly	<u>Actonel:</u> 5 mg/day 35 mg/week 150 mg/month <u>Atelvia:</u> 35 mg/week
ibandronate (Boniva [®])	150 mg PO once monthly	150 mg/month

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): hypocalcemia, hypersensitivity
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PMO	3 mg IV every 3 months	3 mg/3 months

VI. Product Availability

Single-dose prefilled syringe: 3 mg/3 mL

VII. References

1. Ibandronate Sodium Injection Prescribing Information. Weston, FL: Apotex Corp.; September 2024. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9fad4982-95af-d711-f50a-867311835143>. Accessed October 22, 2024.
 2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2023. URL: www.clinicalkeys.com/pharmacology.
- Osteoporosis Diagnosis, Fracture Risk, and Treatment*
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. *Osteoporos 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.
 9. Qaseem A, Hicks LA, Etcheandia-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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1740	Injection, ibandronate sodium, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.	09.14.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.03.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.01.22	02.23
1Q 2024 annual review: added criteria that member must use generic ibandronate injection; clarified failure of “generic” alendronate is preferred; clarified dosage regimens in Appendix B per PI; references reviewed and updated.	10.20.23	02.24
1Q 2025 annual review: no significant changes; 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.

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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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