

Clinical Policy: Ibandronate Injection (~~formerly~~ Boniva)

Reference Number: LA.PHAR.189

Effective Date: 09.18.21

Last Review Date: ~~01.23.26~~03-05-25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

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

****Please note: This policy is for medical benefit****

Description

Ibandronate injection (~~formerly~~ Boniva[®]) is a bisphosphonate.

FDA Approved Indication(s)

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

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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 Louisiana Healthcare Connections that ~~Boniva~~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;~~

~~5-4.~~ Dose does not exceed both of the following (a and b):

- a. 3 mg every 3 months;
- b. 1 syringe every 3 months.

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Approval duration: ~~126~~ months

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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 LA.PMN.255
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 LA.PMN.53

II. Continued Therapy

A. Osteoporosis (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
- ~~3. Member must use generic ibandronate injection, unless contraindicated or clinically significant adverse effects are experienced;~~
- ~~4-3.~~ 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: ~~12~~ months

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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 LA.PMN.255
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 LA.PMN.53

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 LA.PMN.53

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
Oral bisphosphonates		
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 (formerly 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-October 2025~~. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9fad4982-95af-d711-f50a-867311835143>. Accessed October ~~22, 2024~~16, 2025.
 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.

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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, Insogna 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, Etzeandia-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.
10. [US Preventive Services Task Force; Nicholson WK, Silverstein M, Wong JB, et al. Screening for Osteoporosis to Prevent Fractures: US Preventive Services Task Force Recommendation Statement. JAMA. 2025 Feb 11;333\(6\):498-508. doi: 10.1001/jama.2024.27154.](#)

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Commented [NN1]: The ACP Center for Evidence Reviews (CER) at the Portland Veteran Affairs Research Foundation identified 4 new published studies (2–5) and 1 post hoc analysis (6) that met the inclusion criteria of the surveillance search between 1 January 2022 (last search date for version 1 of the living systematic review) and 28 September 2023 (7). The CER’s surveillance (8) describes the studies found and determined that the new studies would not likely change the prior conclusions of the living systematic review for the benefits and harms of any included treatments (7).
The ACP Clinical Guidelines Committee decided that an update of the living systematic review is not warranted at this time, taking into consideration the lack of a signal of any conclusion changing evidence on benefits or harms from the new evidence identified in the surveillance search.

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

Commented [NN2]: The guidance is consistent with the draft recommendation published last year and mostly consistent with the USPSTF’s 2018 recommendation on the topic, but unlike the latter recommendation, the task force does not specifically reference using bone mineral density (BMD) alone as a screening tool in women aged 65 years and older. Risk assessment tools designed to estimate future fracture risk that can be used with or without BMD as a risk factor input include FRAX,8 the Fracture Risk Calculator (FRC),21 and the Garvan Fracture Risk Calculator.

Our criteria currently don't rely solely on BMD to assess fracture risk, so I don't believe any change is required at this time.

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	03.21	09.18.21
References reviewed and updated.	07.22	08.18.22
Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	10.05.23
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	05.06.24	07.29.24
Annual review: no significant changes; references reviewed and updated.	03.05.25	<u>05.19.25</u>

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
<u>Annual review: no significant changes; removed redirection to generic ibandronate as branded Boniva has been discontinued; references reviewed and updated</u>	<u>01.23.26</u>	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

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