Clinical Policy: Ibandronate Injection (Boniva)

Reference Number: LA.PHAR.189
Effective Date: 09.18.21
Last Review Date: 05.06.24
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 (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: 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 Louisiana Healthcare Connections that Boniva 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 ≥ 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:6 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 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. 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

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®)	Actonel: 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 Atelvia: 35 mg PO once weekly	Actonel: 5 mg/day 35 mg/week 150 mg/month Atelvia: 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-use prefilled syringe: 3 mg/3 mL

VII. References

1. Ibandronate Sodium Injection Prescribing Information. Weston, FL: Apotex Corp.; September 2022. Available at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9fad4982-95af-d711-f50a-867311835143. Accessed October 19, 2023.
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. *Osteoporo Int*. 2022 Oct;33(10):2049-2102. doi:10.1007/s00198-021-05900-y. Epub 2022 Apr 28. Erratum in: *Osteroporos 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.

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	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	

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.

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