

Clinical Policy: Ibandronate Injection (Boniva)

Reference Number: ERX.SPA.64

Effective Date: 10.01.16

Last Review Date: 02.22

Line of Business: Commercial, Medicaid

[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:

- Postmenopausal osteoporosis (PMO): Treatment of osteoporosis in postmenopausal women. 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] 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 \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; alendronate is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for oral bisphosphonates*
4. Dose does not exceed 3 mg (1 syringe) every 3 months.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Osteoporosis (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 3 mg (1 syringe) every 3 months.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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
Oral bisphosphonates		
alendronate (Fosamax®)	Treatment/prevention: PMO Treatment: GIO, male osteoporosis Treatment: Paget disease <i>See prescribing information for dose.</i>	Varies
Fosamax® Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis <i>See prescribing information for dose.</i>	
risedronate (Actonel®, Atelvia®)	Actonel: Treatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease Atelvia: Treatment: PMO <i>See prescribing information for dose.</i>	
ibandronate (Boniva®)	Treatment/prevention: PMO <i>See prescribing information for dose.</i>	

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. Boniva Injection Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; April 2019. Available at <https://www.gene.com>. Accessed September 13, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. URL: <http://www.clinicalpharmacology.com>.

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. National Osteoporosis Foundation Clinician’s Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: <https://cdn.nof.org/wp-content/uploads/2016/01/995.pdf>. Accessed September 13, 2021.
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
1Q18 annual review: Converted to new template. Removed requirements for evidence of diagnosis (T-score, history of fracture). Removed age requirement. Modified trial and failure requirements to an oral bisphosphonate and removed definition of treatment failure. Removed requirements regarding last dose of Reclast. Updated appendices, and therapeutic alternatives.	11.14.17	02.18
1Q 2019 annual review: removed requirement that member is a postmenopausal female; added age requirement; references reviewed and updated.	11.01.18	02.19
1Q 2020 annual review: no significant changes; age - added closed epiphyses if younger than 18; 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

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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