

## **Clinical Policy: Ibandronate Injection (Boniva)**

Reference Number: CP.PHAR.189

Effective Date: 11.15.17

Last Review Date: 02.22

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<sup>®</sup>) 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.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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.*
4. Dose does not exceed 3 mg (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**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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. Currently receiving medication via Centene benefit 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:**

**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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less);** or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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/<br>Maximum Dose |
|--|--|-----------------------------|
| <b><i>Oral bisphosphonates</i></b>     |  |                             |
| alendronate<br>(Fosamax <sup>®</sup> ) | Treatment/prevention: PMO<br>Treatment: GIO, male osteoporosis<br>Treatment: Paget disease<br><i>See prescribing information for dose.</i> | Varies                      |

| Drug Name   | Dosing Regimen   | Dose Limit/<br>Maximum Dose |
|---|--|-----------------------------|
| Fosamax <sup>®</sup> Plus D<br>(alendronate /<br>cholecalciferol) | Treatment: PMO, male osteoporosis<br><i>See prescribing information for dose.</i>  |                             |
| risedronate<br>(Actonel <sup>®</sup> , Atelvia <sup>®</sup> )     | Actonel:<br>Treatment/prevention: PMO, GIO<br>Treatment: male osteoporosis<br>Treatment: Paget disease<br>Atelvia:<br>Treatment: PMO<br><i>See prescribing information for dose.</i> |                             |
| ibandronate (Boniva <sup>®</sup> )                                | Treatment/prevention: PMO<br><i>See prescribing information for dose.</i>  |                             |

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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 14, 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.  
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.

5. 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 14, 2021.
6. 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.
7. 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     | P&T Approval Date |
|--|----------|-------------------|
| 1Q18 annual review: policies combined for commercial and Medicaid; removed criteria for evidence of diagnosis; modified trial and failure requirements to an oral bisphosphonate and removed definition of treatment failure; removed requirement regarding admin of last dose of Reclast; removed hypocalcemia monitoring requirement; references reviewed and updated. | 11.15.17 | 02.18             |
| 1Q 2019 annual review: added HIM line of business; added age requirement; revised commercial approval duration to “6 months or to the member’s renewal date, whichever is longer”; added HCPCS code information; references reviewed and updated.  | 11.01.18 | 02.19             |
| 1Q20 annual review: removed HIM disclaimer for HIM NF drugs; 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 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             |

**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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**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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