

Clinical Policy: Ibandronate Sodium (Boniva)

Reference Number: PA.CP.PHAR.189

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for ibandronate sodium (Boniva®) intravenous injection.

FDA Approved Indication(s)

Boniva is indicated for the treatment of osteoporosis in postmenopausal women.

Limitation of use: The safety and effectiveness of Boniva 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

It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that Boniva injection is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis (must meet all):

1. Diagnosis of osteoporosis;
2. Member is a postmenopausal female;
3. Failure of a 12-month trial of an oral bisphosphonate (*alendronate is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 3 mg every 3 months (1 syringe/3 months).

**Requires prior authorization*

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Osteoporosis (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.01) applies;
2. Documentation of positive response to therapy;

3. Prescribed dose does not exceed 3 mg (1 syringe) every three months.

Approval duration: 12 months (four injections)

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.01) applies; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Ibandronate sodium is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. The action of ibandronate on bone tissue is based on its affinity for hydroxyapatite, which is part of the mineral matrix of bone. Ibandronate inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass.

Formulations:

Boniva injection is available as a single-use prefilled syringe containing 3 mg/mL solution.

Appendices

Appendix A: Abbreviation Key

BMD: bone mineral density
 DXA: dual energy X-ray absorptiometry
 Ca: Calcium
 cCa: albumin-corrected calcium

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	Approval Date
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	02/18	

Reviews, Revisions, and Approvals	Date	Approval Date
Reclast. Removed hypocalcemia monitoring requirement. References reviewed and updated.		

References

1. Boniva Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2016. Available at https://www.gene.com/download/pdf/boniva_injection_prescribing.pdf. Accessed November 14, 2017.
2. Cosman F, de Beur SJ, LeBoff MS, et al. Position paper: clinician’s guide to prevention and treatment of osteoporosis. *Osteoporosis Int.* 2014; 25(10): 2359-2381.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. *Endocrin Pract.* 2016; 22(Suppl 4).
4. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guidelines. *J Clin Endocrinol Metab* 2012;97(6):1802-1822.
5. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract* 2010;16(Suppl 3):1-37.