Clinical Policy: Ibandronate Sodium (Boniva)

Reference Number: PA.CP.PHAR.189
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

Description
Ibandronate injection (Boniva®) is a bisphosphonate.

FDA Approved Indication(s)
Boniva is indicated for the 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 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. Age ≥ 18 years;
3. Member is a postmenopausal female;
4. 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;
5. Dose does not exceed 3 mg every 3 months (1 syringe per 3 months).

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. Member is responding positively to therapy;

3. If request is for a dose increase, new does not exceed 3 mg every 3 months (1 syringe per 3 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.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMD: bone mineral density
FDA: Food and Drug Administration

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
alendronate (Fosamax®)	Osteoporosis 10 mg PO QD or 70 mg PO q week Glucocorticoid-induced osteoporosis 5 mg PO QD or 10 mg PO QD (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg PO QD or 35 mg PO q week	Osteoporosis 10 mg/day or 70 mg/week Glucocorticoid-induced osteoporosis 5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg/day or 35 mg/week
Fosamax® Plus D (alendronate/ cholecalciferol)	Osteoporosis 70 mg alendronate/2,800 units cholecalciferol or 70 mg	70 mg alendronate/5,600 units cholecalciferol/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	alendronate/5,600 units cholecalciferol PO q week	
risedronate (Actonel®, Atelvia®)	Osteoporosis (including prophylaxis) 5 mg PO QD or 35 mg PO q week or 75 mg PO QD for 2 consecutive days for 2 doses/month or 150 mg PO q month Glucocorticoid-induced osteoporosis 5 mg PO QD	Osteoporosis (including prophylaxis) 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month Glucocorticoid-induced osteoporosis 5 mg/day
ibandronate (Boniva®)	Osteoporosis (including prophylaxis) 150 mg PO q month	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

Appendix D: General Information

- The World Health Organization uses the following classifications for osteoporosis and osteopenia:

Category	T-score
Normal	-1.0 or above
Low bone mass (osteopenia)	Between -1.0 and -2.5
Osteoporosis	-2.5 or below

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Osteoporosis	3 mg IV every 3 months	3 mg/3 months

V. Product Availability

Single-use prefilled syringe: 3 mg/3 mL

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 Reclast. Removed hypocalcemia monitoring requirement. References reviewed and updated.	02/18	
1Q 2019 annual review: added age requirement; added HCPCS code information; references reviewed and updated.	01/19	

References

1. Boniva Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2016. Available at https://www.gene.com. Accessed November 1, 2018.
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.
6. American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. Ann intern Med. 2017; 166: 818-839.