Clinical Policy: Ibandronate Oral (Boniva®)

Reference Number: PA.CP.PMN.96
Effective Date: 03.01.18
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Revision Log

Description
Ibandronate (Boniva®) is an oral bisphosphonate.

FDA Approved indication(s)
Boniva is indicated for the treatment and prevention of postmenopausal osteoporosis.

Limitation of use: The optimal duration of use for bisphosphonates has not been determined. The safety and effectiveness of bisphosphonates for the treatment of osteoporosis are based on clinical data of one to four years duration. 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
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness that oral Boniva is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. **Osteoporosis** (must meet all)**:**
    1. Prescribed for the prophylaxis or treatment of osteoporosis;
    2. Age ≥ 18 years;
    3. Failure of alendronate at up to maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
    4. Dose does not exceed 150 mg/month (1 tablet/month).

    Approval duration: 12 months

2. **Other diagnoses/indications**
    Refer to PA.CP.PMN.53 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 PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 150 mg/month (1 tablet/month).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PMN.53 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 – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
MO: male osteoporosis
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 for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	PMO/MO treatment: 10 mg PO QD or 70 mg PO once weekly PMO Prevention: 5mg PO QD or 35 mg PO once weekly Paget's disease: 40 mg PO QD for 6 months	40 mg/day 70 mg/week

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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ibandronate (Boniva)	150 mg orally once monthly on the same day each month	150 mg/month

VI. Product Availability

Tablet: 150mg

VII. References

1. Boniva Prescribing Information. South San Francisco, CA: Genentech USA, Inc. October 2015. Available at https://www.gene.com/. Accessed December 2017.
2. Camacho PM, Petak SM, Brinkley N et al. AACE/ACE Guidelines- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol 22 (suppl 4) September 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date