CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Boniva (ibandronate) injection
BILLING CODE	J1740
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient hospital
COVERAGE REQUIREMENTS	Prior Authorization Required for injectable product only (no Prior Authorization needed for oral product) Alternative preferred products include zoledronic acid QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Boniva (ibandronate) injection is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOPOROSIS

For **initial** authorization:

1. Medication is intended to be used for treatment of osteoporosis in postmenopausal women with high risk for fracture;
2. Member's osteoporosis evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total, and/or 33% (one-third) radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia or low bone mass (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or possibly distal forearm;
   d) Osteopenia or low bone mass and high FRAX® fracture probability (a 10-year probability for major osteoporotic fracture is ≥ 20% or the 10-year probability of hip fracture is ≥ 3%); AND
3. Member does **not** have ANY of the following:
   a) Uncorrected hypocalcemia;
   b) Dental disease;
   c) History of receiving Xgeva within the past 6 months; AND
4. Member was instructed to take calcium 1,000 mg daily and at least 400 IU of vitamin D daily; AND
5. Documentation of member's inability to take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) required as evidenced by one or more of the following:
   a) Esophogeal dysmotility or varices;
   b) Member is unable to stand or sit upright for 30-60 minutes;
   c) Presence of anatomic or functional esophageal abnormalities that might delay tablet transit (e.g., achalasia, stricture, or dysmotility);
   d) Presence of documented or potential GI malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.);
   e) Member has experienced intolerance to or treatment failure of one or more bisphosphonate medications;
   f) Member has a history of non-adherence to oral bisphosphonate medications; AND

6. Member has had a documented trial and inadequate response to zoledronic acid.
7. **Dosage allowed:** IV: 3 mg every 3 months.

Note: IV form of the drug is only indicated for treatment (not prevention) of osteoporosis in postmenopausal women.

If member meets all the requirements listed above, the medication will be approved for 12 months

For **reauthorization**:
1. Member meets all initial criteria; AND
2. Chart notes have been provided that show the member has shown an increase in bone mineral density.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Boniva (ibandronate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Bone metastases from solid tumors
- Giant Cell Tumor of Bone
- Multiple Myeloma
- Paget's disease
- Bone loss (for nonmetastatic prostate cancer or for breast cancer)

DATE	ACTION/DESCRIPTION
07/29/2019	New policy for Boniva injection created.

References:

1. Bonia [prescribing information]. South San Francisco, CA: Genentech, Inc.; April, 2019.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. Endocr Pract. 2016;22(Suppl 4). Doi: 10.4158/EP161435.GL.
3. Tu KN, Lie JD, Wan CKV, et al. Osteoporosis: A Review of Treatment Options. P&T. 2018 Feb; 43(2): 92–104.
4. Porter JL, Varacallo M. Osteoporosis. StatPearls Publishing LLC. Bookshelf ID: NBK441901, PMID: 28722930. Available at: https://www.researchgate.net/profile/Matthew_Varacallo/publication/329717790_Osteoporosis/links/5c17f5314585157ac1ca042b/Osteoporosis.pdf?origin=publication_detail.

Effective date: 09/26/2019
Revised date: 07/29/2019

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Appendix. Risk Factors for Fracture:

1. Prior fracture;
2. Age ≥ 65;
3. Low body weight (< 57.6 kg [127 lb]);
4. Family history of osteoporosis or fractures;
5. Smoking;
6. Early menopause;
7. Excessive alcohol intake (≥ 3 drinks daily);
8. Rheumatoid arthritis (confirmed diagnosis);
9. Secondary osteoporosis (e.g., type 1 diabetes, hypothyroidism, chronic liver disease);
10. Height loss (including unexplained) or kyphosis;
11. Patient's reliability, understanding, and willingness to accept interventions;
12. Glucocorticoid therapy equivalent to ≥ 5 mg prednisone daily for 3 months or more;
13. Risk factors for falling*

*Risk factors for falling can be any of the following:

- Neurologic disorders (e.g., Parkinson disease, seizure disorder, peripheral neuropathy, prior stroke, dementia, impaired gait and/or balance, autonomic dysfunction with orthostatic hypotension);
- Impaired vision;
- Impaired hearing;
- Frailty and deconditioning;
- Proximal myopathy;
- Sarcopenia;
- Medications (e.g., sedatives and hypnotics, antihypertensive agents, narcotic analgesics);
- Environmental factors (e.g., poor lighting, stairs, slippery floors, wet, icy, or uneven pavement, uneven roadways, electric or telephone cords, walking large dogs, being tripped up by small dogs, throw rugs, positioning in a wet or dry bathtub).