Clinical Policy: Ibandronate (Boniva)
Reference Number: ERX.SPMN.106
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that ibandronate (Boniva® and generic formulations) intravenous injection is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Osteoporosis (must meet all):
      1. Age ≥ 18 years;
      2. Diagnosis of postmenopausal osteoporosis defined as a or b:
         a. T-score ≤ -2.5 (DXA) at the femoral neck or spine;
         b. History of osteoporotic fracture;
      3. Had an inadequate response (decline in BMD of ≥5% or continued fractures after one year of therapy) to oral bisphosphonate therapy, unless contraindicated or intolerant;
      4. If member has received Reclast (zoledronic acid), one year has passed since use of Reclast;
      5. Member is receiving supplemental calcium and vitamin D if dietary intake is inadequate;
      6. Prescribed dose of ibandronate injection does not exceed 3 mg (one injection) every three months.

       Approval duration: 6 months (two injections)

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval
   A. Osteoporosis (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria.

       Approval duration: 12 months (four injections)

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.
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.

FDA Approved Indication:
Boniva injection is a bisphosphonate/intravenous injectable indicated for:
- Treatment of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, Boniva increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

Limitations 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.

Appendices

Appendix A: Abbreviation Key
BMD: bone mineral density
DXA: dual energy X-ray absorptiometry

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.

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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J1740</td>
<td>Injection, ibandronate sodium, 1 mg</td>
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Reviews, Revisions, and Approvals

Policy split from USS.CP.PHAR.20 Osteoporosis Injectable Therapy and converted to new template. | Date | Approval Date |
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Reviews, Revisions, and Approvals

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<th>Criteria</th>
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<td>Removed safety criteria. Added “at femoral neck or spine” to T score. Removed requirement that must be over 50 in cases where the osteoporosis diagnosis relies on history of an osteoporotic fracture. Added definition of bisphosphonate trial failure. Removed preferencing for Reclast as ibandronate injection is PDL. Calcium/vitamin D requirement language edited to be less specific. Approval period changed to 6 and 12 months.</td>
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References


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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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