Clinical Policy: Ibandronate Injection (Boniva)
Reference Number: CP.CPA.230
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Commercial

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

Description
Ibandronate injection (Boniva®) is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption.

FDA approved indication
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
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 Centene Corporation® that Boniva is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Postmenopausal Osteoporosis (PMO) (must meet all):
      1. Diagnosis of postmenopausal osteoporosis;
      2. Failure of a bisphosphonate (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced;
      3. Dose does not exceed 3 mg every 3 months.

   Approval duration: Length of Benefit

   B. Other diagnoses/indications
      1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy
   A. Postmenopausal Osteoporosis (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed: 3 mg every 3 months.

**Approval duration: Length of Benefit**

B. **Other diagnoses/indications** (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      **Approval duration: Duration of request or 12 months (whichever is less); or**
   2. Refer to CP.CPA.09 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 – CP.CPA.09 or evidence of coverage documents.

IV. **Appendices/General Information**

   **Appendix A: Abbreviation/Acronym Key**
   PMO: Postmenopausal Osteoporosis

   **Appendix B: General Information**
   - Boniva should not be used in a patient with uncorrected hypocalcemia.
   - According to the National Osteoporosis Foundation, there are few indications for combining two antiresorptive treatments, but such options could be considered in the short-term in women who are experiencing active bone loss while on low dose hormone therapy for menopausal symptoms or raloxifene for breast cancer prevention.

   **Appendix C: Therapeutic Alternatives**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate (Fosamax®)</td>
<td>PMO treatment: 10 mg PO QD or 70 mg PO once weekly</td>
<td>10 mg/day 70 mg/week</td>
</tr>
<tr>
<td>Alendronate/cholecalciferol</td>
<td>PMO treatment: 70 mg alendronate/2800IU cholecalciferol or 70 mg alendronate/5600IU cholecalciferol PO once weekly</td>
<td>70 mg alendronate/5,600IU cholecalciferol/week</td>
</tr>
<tr>
<td>Risedronate (Actonel®)</td>
<td>PMO treatment 5 mg po QD or 35 mg PO once weekly or 75 mg po QD taken on two</td>
<td>5 mg/day 35 mg/week 150 mg/month</td>
</tr>
</tbody>
</table>
## CLINICAL POLICY

### Ibandronate

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raloxifine (Evista®)</td>
<td>PMO treatment: 60 mg PO QD</td>
<td>60 mg/day</td>
</tr>
<tr>
<td>Calcitonin-Salmon nasal spray</td>
<td>PMO treatment: 200 IU spray in one nostril QD</td>
<td>Nasal Spray: 200 IU/day</td>
</tr>
<tr>
<td>(Miacalcin® Nasal Spray, Fortical® Nasal Spray)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcitonin-Salmon (Miacalcin® Injection)</td>
<td>PMO treatment: 100 IU SC/IM QOD</td>
<td>Injection: 100 IU/day</td>
</tr>
<tr>
<td>Teriparatide (Forteo®)</td>
<td>PMO treatment: 20 mcg SC QD</td>
<td>20 mcg QD for 2 years</td>
</tr>
<tr>
<td>Denosumab (Prolia®)</td>
<td>PMO treatment: 60 mg SC once every 6 months Prolia should be administered by a healthcare professional.</td>
<td>60 mg per dose once every 6 months</td>
</tr>
<tr>
<td>Zoledronic acid (Reclast®)</td>
<td>PMO treatment: 5 mg IV infusion over at least 15 minutes once yearly</td>
<td>PMO Treatment: 5mg per dose once yearly</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMO treatment</td>
<td>3 mg IV infusion over 15-30 seconds every 3 months Boniva should be administered by a healthcare professional.</td>
<td>3 mg every 3 months</td>
</tr>
</tbody>
</table>

## VI. Product Availability

Single-use prefilled syringe: 3 mg/3mL

## VII. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar. References updated.</td>
<td>07.05.17</td>
<td>11.17</td>
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**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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