Boniva® (ibandronate) IV
(Intravenous)

Last Review Date: 1/3/2018
Date of Origin: 11/28/2011

I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - 3 mg prefilled syringe once per 12 weeks

B. Max Units (per dose and over time) [Medical Benefit]:
   - 3 billable units every 12 weeks

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Treatment of women with postmenopausal osteoporosis †

- Patient is 18 years or older: AND
- Patient is receiving concurrent calcium and Vitamin D supplementation: AND
- Patient must not have hypocalcemia: AND
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  o Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) radius: OR
  o T-score ≤ -1 or low bone mass and a history of fragility fracture to the hip or spine: OR
  o T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; AND
- Patient must be at a high risk for fracture**: AND
  o Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, or ibandronate: OR
  o Patient has a documented contraindication* or intolerance to oral bisphosphonates such as alendronate, risedronate, or ibandronate

±Ineffective response is defined as one or more of the following:
- Decrease in T-score in comparison with baseline T-score from DXA scan
- Patient has a new fracture while on bisphosphonate therapy

**High risk for fractures include, but are not limited to, one or more of the following:
- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake (3 or more drinks per day)
- Current smoking
- History of oral glucocorticoids ≥5 mg/d of prednisone for >3 months (ever)

*Examples of contraindications to oral bisphosphonate therapy include the following:*
- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett’s esophagus, esophageal stricture, dysmotility, or achalasia

† FDA-labeled indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria indicated in Section III; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypocalcemia, anaphylaxis, renal toxicity, severe bone joint or muscle pain, atypical femur fracture, osteonecrosis of jaw (ONJ), etc.; AND
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment baseline

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postmenopausal osteoporosis</td>
<td>3 mg intravenously every 3 months (12 weeks)</td>
</tr>
<tr>
<td></td>
<td>• Optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3 to 5 years of use</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

**Jcode:**
J1740 – Injection, ibandronate sodium, 1 mg; 1 mg = 1 billable unit

**NDC:**
Boniva 3 mg/3 mL single-use prefilled syringe: 00004-0191-xx

*Generic formulation available from various manufacturers*

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M80.00XA-M80.08XS</td>
<td>Age-related osteoporosis with current pathological fracture</td>
</tr>
<tr>
<td>M81.0</td>
<td>Age-related osteoporosis without current pathological fracture</td>
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</table>

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

<table>
<thead>
<tr>
<th>Jurisdiction(s):</th>
<th>NCD/LCD Document (s):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L33270</td>
</tr>
</tbody>
</table>
This HNE clinical criteria is only a screening tool. It is not for final clinical or payment decisions. All care decisions are solely the responsibility of your healthcare provider. This HNE clinical criteria is confidential and proprietary. It applies only to this review.

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**Jurisdiction(s):** 5, 8  
**NCD/LCD Document(s):** L34648


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**Jurisdiction(s):** 6, K  
**NCD/LCD Document(s):** A52421


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**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
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<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
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<tr>
<td>8</td>
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<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
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<tr>
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<td>Cahaba Government Benefit Administrators, LLC</td>
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<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
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<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
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<td>K (13 &amp; 14)</td>
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<td>15</td>
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<td>CGS Administrators, LLC</td>
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