I. POLICY

Preauthorization may be required, determine prior to treatment.

Note: The maximum initial authorization will be for one year. Maintenance therapy will be authorized on a yearly basis.

Ibandronate Sodium (Boniva®) is approved by the U.S. Food and Drug Administration (FDA) for the following indication: Treatment of osteoporosis in postmenopausal women.

Note: The safety and effectiveness of injectable Ibandronate (Boniva®) is not established in pediatric patients.

Injectable ibandronate (Boniva®) may be considered medically necessary for the treatment of osteoporosis in postmenopausal women who have contraindications or are unresponsive to oral osteoporosis agents, are receiving supplemental calcium and vitamin D and any ONE of the following indications are met:

- Presence or history of osteoporotic fracture.
- Bone mineral density (BMD) T score of [-2.0] or less at the femoral neck or spine after appropriate evaluation to exclude secondary causes.

The inability to swallow tablets is not a medically necessary indication for injectable ibandronate (Boniva®) as alternative preparations of oral bisphosphonates are available (e.g. liquid alendronate).

The use of injectable ibandronate (Boniva®) for non-FDA approved indications is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.
II. PRODUCT VARIATIONS  

[N] = No product variation, policy applies as stated  
[Y] = Standard product coverage varies from application of this policy, see below

- [N] Capital Cares 4 Kids  
- [N] Indemnity  
- [N] PPO  
- [N] SpecialCare  
- [N] HMO  
- [N] POS  
- [Y] SeniorBlue HMO*  
- [Y] FEP PPO**  
- [Y] SeniorBlue PPO*

* FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.” Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.2- Unlabeled Use of Drug).  

** The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND  

Bisphosphonates  
Bisphosphonates suppress bone resorption and are the most widely used class of drugs to treat osteoporosis.

Oral bisphosphonates such as Alendronate (Fosamax®) and Risedronate (Actonel®) are available in daily or weekly dosages. Ibandronate (Boniva®) is available in an oral and injectable form for daily or monthly dosing. Oral bisphosphonates can cause gastrointestinal disorders and patients must remain upright for thirty minutes (Alendronate and Risedronate) or sixty minutes (Ibandronate) after swallowing the tablet whole with plain water on an empty stomach. Alendronate is also available as an oral liquid for individuals who have difficulty swallowing tablets. Injectable bisphosphonates provide an alternative for individuals who have difficulty with the dosing requirements of oral bisphosphonates. Studies are currently ongoing to determine the appropriate duration of bisphosphonate therapy for osteoporosis.

Ibandronate Sodium (Boniva®) Injection  
Ibandronate (Boniva®) injection is FDA approved for the treatment of osteoporosis in postmenopausal women. Injectable bisphosphonates provide an alternative for individuals who...
have difficulty with the dosing requirements of oral bisphosphonates. The recommended dose of Ibandronate (Boniva®) injection for the treatment of postmenopausal osteoporosis is 3 mg intravenously every 3 months administered over 15-30 seconds in a physician office setting.

**Note:** The safety and effectiveness of Boniva for the treatment of osteoporosis are based on clinical data of three years duration. The optimal duration of use has not been determined. Patients should have the need for continued therapy re-evaluated on a periodic basis.

Atypical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate-treated patients. These fractures can occur anywhere in the femoral shaft and most commonly occur with minimal or no impact to the affected areas. They may be bilateral and many patients report prodromal pain in the affected areas, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of the fracture.

Any patient with a history of bisphosphonate exposure who presents with thigh or groin pain should be suspected of having atypical fracture and should be evaluated to rule out a femur fracture. Subjects presenting with an atypical fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of bisphosphonate therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Emerging evidence has also indicated a link between bisphosphonates and a rare but serious complication, osteonecrosis of the jaw. This may be more likely to occur after oral surgery.

**Osteoporosis**

Osteoporosis is characterized by decreased bone mass and increased fracture risk, most commonly at the spine, hip and wrist. The diagnosis can be confirmed by a finding of low bone mass or by the presence or history of osteoporotic fractures. Osteoporosis is most common among post-menopausal women but can occur in men as well.

Bone mineral density (BMD) is one of the key determinants for the need for drug therapy and may be classified according to the T score. A T score is the comparison of an individual’s bone density to the optimal peak bone density for the individual’s gender. It is reported as number of standard deviations (SD) below the average. The World Health Organization (WHO) defines osteoporosis as spine, hip, or wrist bone mineral density (BMD) 2.5 SD or more below the young adult mean (T score of [-2.5] or less). The FDA indicates osteoporosis may be confirmed by the presence or history of osteoporotic fracture or by a finding of low bone mass (BMD more than 2.0 standard deviations below the premenopausal mean [ie, T score]). Osteopenia is a condition where bone mineral density is lower than normal but not as low as osteoporosis. It is defined as a T score between [-1.0 and -2.5].

Dual Energy X-ray Absorptiometry (DEXA) is the most commonly used technique to measure BMD. The margin of error of repeated DEXA tests is 3-5% and the average person will not have a change of this magnitude over a 3-5 year period. Also, DEXA result norms are
established for each individual machine and therefore, repeat testing on another machine is not directly comparable.

IV. DEFINITIONS

**Bone Resorption** is bone loss due to osteoclastic activity.

**Fracture** is a traumatic injury to a bone in which the continuity of the bone tissue is broken.

**Menopause** is the cessation of menses as a result of failure of follicular maturation in the presence of elevated gonadotropin.

**Morphometric Fracture** is a fracture identified by a change in the shape of a bone, rather than from pain or other symptoms.

**Off-Label Use** is the use of a prescription drug or medical device in the treatment of an illness or injury for which it has not been specifically approved by the FDA.

**Osteoclastic** refers to osteoclasts, especially with reference to their activity in the absorption and removal of osseous (bone) tissue.

**Osteoclasts** are large multinucleated cells formed from differentiated macrophages that are responsible for the breakdown of bone.

V. **Benefit Variations**

The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.
VI. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES


Colón-Emeric CS. Ten vs Five Years of Bisphosphonate Treatment for Postmenopausal Osteoporosis: Enough of a Good Thing JAMA, December 27, 2006; 296: 2968 - 2969.


VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

<table>
<thead>
<tr>
<th>HCPSC Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1740</td>
<td>INJECTION, IBANDRONATE SODIUM, 1 MG</td>
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<table>
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<tr>
<th>ICD-9-CM Diagnosis Code*</th>
<th>Description</th>
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<tr>
<td>733.00</td>
<td>UNSPECIFIED OSTEOPOROSIS</td>
</tr>
<tr>
<td>733.01</td>
<td>SENILE OSTEOPOROSIS</td>
</tr>
<tr>
<td>733.02</td>
<td>IDIOPATHIC OSTEOPOROSIS</td>
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<tr>
<td>733.03</td>
<td>DISUSE OSTEOPOROSIS</td>
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<tr>
<td>733.09</td>
<td>OTHER OSTEOPOROSIS</td>
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<tr>
<td>733.10-733.19</td>
<td>PATHOLOGICAL FRACTURE</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code*</th>
<th>Description</th>
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<tbody>
<tr>
<td>M81.0</td>
<td>Age-related osteoporosis without current pathological fracture</td>
</tr>
<tr>
<td>M81.06</td>
<td>Localized osteoporosis [Lequesne]</td>
</tr>
<tr>
<td>M81.08</td>
<td>Other osteoporosis without current pathological fracture</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. POLICY HISTORY

<table>
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<tr>
<td>CAC 6/26/07</td>
<td>CAC 5/27/08</td>
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<tr>
<td>CAC 5/26/09</td>
<td>Config Meeting 1/09 (Added Zometa)</td>
</tr>
<tr>
<td>CAC 1/25/2011</td>
<td>CAC 5/26/09</td>
</tr>
</tbody>
</table>
| CAC 5/25/2011 | The FDA label language regarding pediatric use (“Safety and effectiveness of injectable ibandronate [Boniva®] in pediatric patients is not
established.”) was added. Changed “history of hip or vertebral fracture “statement to “presence or history of osteoporotic fracture” to match FDA indication. Changed osteoporosis definition from T score of -2.5 to -2.0 to match FDA. Removed statement “Substitution of injectable ibandronate sodium (Boniva®) when done solely for the convenience purposes is considered not medically necessary”. Added information related to optimal duration of treatment and risk of low trauma fractures of the femoral shaft in bisphosphonate-treated patients in the Background/Description section.

CAC 4/24/2012 Consensus. No changes
CAC 6/4/13 Consensus list review. No coding changes.