Medical Coverage Policy

Intravenous Bisphosphonate for the Treatment of Osteoporosis-PREAUTH

☐ Device/Equipment ☒ Drug ☐ Medical ☐ Surgery ☐ Test ☐ Other

| Effective Date: | 3/4/2008 | Policy Last Updated: | 3/20/2012 |

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

This policy refers to the use of intravenous bisphosphonates for the treatment of osteoporosis.

Description:

**Osteoporosis**

The World Health Organization (WHO) has defined osteoporosis on the basis of bone mineral density (BMD) measurements to help identify individuals at risk. The bone density DXA test is one that measures the bone mineral density and compares it to an established norm or standard resulting in a score. The results are compared to the ideal or peak bone mineral density of a healthy 30-year-old adult called a T-score. A T-score is the number of standard deviations (SD) the BMD measurement is above or below the young adult mean bone mineral density.

A T-score between +1 and −1 is considered normal or healthy. A T-score between −1 and −2.5 indicates that you have low bone mass (osteopenia), although not low enough to be diagnosed with osteoporosis. A T-score of −2.5 or lower indicates that you have osteoporosis. The greater the negative number, the more severe the osteoporosis.

**Therapeutic Medications**

Medications are available for the treatment of osteoporosis. Several are nitrogen-containing biophosphonates (e.g., ibandronate sodium, (Boniva™), zoledronic acid (Reclast™), etc.) which inhibit osteoclast-mediated bone resorption and are used to treat post-menopausal osteoporosis by increasing bone mass. These medications may be administered orally (daily, weekly, or monthly) or by injection. In addition to its use in the treatment of post-menopausal osteoporosis, zoledronic acid is used in the treatment of Pagets disease and hypercalcemia associated with some cancers, however this policy only addresses treatment of osteoporosis.

The US Food and Drug Administration (FDA) has approved Reclast (zoledronic acid) therapy once every two years to prevent post-menopausal osteoporosis. However, there is inadequate data to provide clinical evidence that Reclast can prevent osteopenia which can lead to osteoporosis in post-menopausal women.
Medical Criteria:
Intravenous bisphosphonate treatment for osteoporosis is considered medically necessary for patients with osteoporosis who have a documented contraindication or intolerance to oral bisphosphonates based on the following criteria:

- Patient has a diagnosis of esophageal stricture, achalasia, or other severe esophageal dysmotility disorder; OR
- Patient has a history of severe malabsorption making use of oral bisphosphonates ineffective; OR
- Patient has an inability to stand or sit upright for 60 minutes; OR
- Patient has tried and is intolerant to two (2) or more oral bisphosphonates.

Gastroesophageal reflux (GERD) and dyspepsia diagnoses in the absence of the above criteria are not considered a contraindication to oral bisphosphonates.

The clinician requesting medical review should document in the record the specific reasons why oral therapy is medically contraindicated.

Zoledronic acid (Reclast™) for osteopenia (low bone mass) is considered **not medically necessary** because its effectiveness has not been established.

The FDA has approved the use of zoledronic acid for the treatment of Paget's disease and hypercalcemia associated with some cancers. This policy does not address those treatments; however zoledronic acid is covered for treatment of Paget's disease and hypercalcemia.

Policy:
Intravenous administration of ibandronate sodium or zoledronic acid is medically necessary when the member meets at least one of the criteria listed above and the use of the drug is for the treatment of osteoporosis.

**Preauthorization is required for BlueCHiP for Medicare and recommended for all other BCBSRI products.**

Coverage:
Benefits may vary between groups/contract. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable infusion benefit/coverage and prescription drug benefit/coverage.

Specialty Pharmacy:
For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorizations guidelines.

Coding:
The following codes are covered with **preauthorization**:
J1740 Injection, ibandronate sodium, 1 mg
J3488 Injection, Zoledronic acid (reclast), 1 mg

The following code is covered for **Paget's disease and hypercalcemia associated with some cancers** and **does not require preauthorization**:
J3487 Injection, Zoledronic acid (zometa), 1 mg
Also known as:
Boniva IV™
Reclast™
Zometa™

Related topics:
Denosumab (Prolia) for Postmenopausal Osteoporosis

Published:
Policy Update, July 2006
Policy Update, July 2007
Policy Update, December 2007
Provider Update, April 2008
Provider Update, May 2009
Provider Update, July 2010
Provider Update, July 2011
Provider Update, June 2012

References:
Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD) for Bisphosphonate Drug Therapy (L30139) Accessed 2/22/2012.

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