

Boniva® (ibandronate sodium)

When requesting Boniva® (ibandronate sodium), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Treatment of osteoporosis in postmenopausal women.

Coverage Guidelines

Treatment of Osteoporosis in Postmenopausal Women

The individual must meet **all** of the following criteria for approval:

- Is at high risk for fracture, defined as one or more of the following:
 - History of osteoporotic fracture or a fragility fracture;
 - Has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
 - Has low bone mass (e.g., T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% [one-third] radius [wrist]) AND is at high risk for fracture; AND
- Meets one of the following criteria:
 - Has experienced inadequate efficacy to oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase);
 - Has experienced intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events, severe musculoskeletal-related adverse events, a femoral fracture);
 - Is unable to take an oral bisphosphonate due to one of the following conditions: 1) cannot swallow or has difficulty swallowing, 2) cannot remain in an upright position post oral bisphosphonate administration; 3) has a pre-existing gastrointestinal medical condition (e.g., esophageal lesions, esophageal ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]); OR
 - Has tried an IV bisphosphonate agent (e.g., zoledronic acid injection [Reclast]); AND
- Has a serum calcium or corrected calcium greater than or equal to normal per reference range OR is receiving calcium supplementation; AND
- Has a creatinine clearance greater than or equal to 30 ml/min.

For reauthorization, the individual must meet **all** of the criteria above AND has experienced at least one of the following with the use of Boniva:

- Stability;
- Reduction in vertebral fractures; OR
- Increase in bone mineral density.

Approval duration: 12 months

Recommended Dosing

Approve up to a maximum of 3 mg, administered intravenously, once every 3 months.

References

1. Boniva prescribing information. San Francisco, CA: Genentech Inc.: Revised April 2019. Accessed May 3, 2021.
2. Camacho PM, Petak SM, et al. AACE medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2020; 26 Suppl 1. Accessed September 23, 2020.
3. World Health Organization. FRAX® WHO fracture risk assessment tool. Available at: <https://www.shef.ac.uk/FRAX/>. Accessed September 23, 2020.
4. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. Accessed September 23, 2020.