



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 23, 2009 October 6, 1009 February 4, 2011; April 12, 2012, November 12, 2015

BONIVA® (ibandronate) injection

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

INITIATION OF THERAPY:

- Documented diagnosis of osteoporosis with A DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past year). (*Must be confirmed in medical records.*) **-OR-**
- History of a fracture of the spine or hip. (*Must be confirmed in medical records.*) **-OR-**
- History of T-score between -1.0 and -2.5 if FRAX (WHO Fracture Risk Assessment Tool) major osteoporotic fracture probability is $\geq 20\%$ or hip fracture probability is 3%. (*Must be confirmed in medical records.*)

-AND-

- Office notes documenting an intolerance to oral bisphosphonates due to:
 - Inability to take medications by mouth or
 - Severe upper GI disease (eg. erosive esophagitis, peptic ulcers with history of bleeding)

-OR-

- Office notes documenting a treatment **trial (minimum 6 months)** and failure of
 - Boniva oral tablet monthly administration as indicated by no change from baseline BMD **-OR-**
 - Failure after a six month trial of the preferred oral bone resorption inhibitor monthly administration as indicated by no change from baseline BMD.



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CONTINUATION OF THERAPY:

- Medical records must demonstrate a stable BMD (within interventional goals) or an increasing BMD after a minimum trial of one year of therapy.
 - T-score test results may date back as far as five years.
 - Depending on level of BMD progression retesting may be done from every one to five years.
 - Medical records should demonstrate improvement by providing reference to the sequential progression or stability of the BMD.

DOSING:

Adults: 3 mg IV bolus every 3 months. The IV bolus should be administered over 15—30 seconds. Do not administer more often than every 3 months. If the dose is missed, administer the dose as soon as possible and schedule future injections every 3 months from that date. Patients must receive supplemental calcium and vitamin D.

LIMITS: ONE INJECTION EVERY 84 DAYS