Division: Pharmacy Services	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, September 2, 2020, July 10, 2023, January 24, 2024

BONIVA® (ibandronate) injection

LENGTH OF AUTHORIZATION: **UP TO ONE YEAR**

REVIEW CRITERIA:

- Prescribed by or in consultation with a specialist (endocrinologist, rheumatologist, obstetrician/gynecologist, or primary care physician) –**AND-**
- Documented diagnosis of osteoporosis with A DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past 2 years). ***(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 ≥ 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.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- 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 is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 3 mg/3 mL (1 mg/mL) single-dose prefilled syringe.

LIMITS: ONE INJECTION EVERY 84 DAYS