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 ≥ 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:

- 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