CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Bone Modifiers – Ibandronate Intravenous Utilization Management Medical Policy
- ibandronate intravenous infusion – generic

REVIEW DATE: 03/04/2026

OVERVIEW

Ibandronate injection is indicated for the treatment of **osteoporosis** in postmenopausal women.[1]

Limitations of Use: The safety and effectiveness of ibandronate sodium injection for the treatment of osteoporosis are based on clinical data of one year duration.[1] The optimal duration of use has not been determined. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of ibandronate injection. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of ibandronate injection is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Osteoporosis – Treatment for a Postmenopausal Patient.** Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
   - **A)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
     - **ii.** Patient has had an osteoporotic fracture or a fragility fracture; OR
     - **iii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has low bone mass; AND
         Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist).
       - **b)** According to the prescriber, patient is at high risk for fracture; AND
   - **B)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried ibandronate injection (Boniva) or zoledronic acid injection (Reclast); OR

ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
- **a)** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
  Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
- **b)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
  Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.

iii. Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
- **a)** Patient cannot swallow or has difficulty swallowing; OR
- **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
- **c)** Patient has a pre-existing gastrointestinal medical condition in which intravenous bisphosphonate therapy may be warranted; OR
  Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient has had an osteoporotic fracture or a fragility fracture.

Dosing. Approve 3 mg administered intravenously no more frequently than once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ibandronate injection is not recommended in the following situations:

1. **Osteoporosis Prevention.** Ibandronate injection is not indicated for the prevention of osteoporosis and supporting data are limited.

2. **Concurrent Use of Ibandronate Injection with Other Medications for Osteoporosis.**
   Note: Examples of medications for osteoporosis that ibandronate injection should not be given with include oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), other intravenous bisphosphonates (e.g., zoledronic acid injection [Reclast]), Prolia (denosumab subcutaneous injection), Evenity (romosozumab-aqqg subcutaneous injection), Forteo (teriparatide subcutaneous injection, generic), Tymlos® (abaloparatide subcutaneous injection), and calcitonin nasal spray. However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with ibandronate injection.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. ibandronate intravenous infusion [prescribing information]. Weston, FL: Apotex; January 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/13/2024
Update	03/31/2024: No criteria changes. Removed the brand name of Boniva from the policy and noted that ibandronate intravenous infusion is available only as a generic.	N/A
Annual Revision	No criteria changes.	03/19/2025
Annual Revision	No criteria changes.	03/04/2026