

**POLICY:** Bone Modifiers – Ibandronate IV (Boniva IV) [Boniva® {ibandronate injection} – Genentech/Roche, generics]

**APPROVAL DATE:** 02/27/2019

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### OVERVIEW

Ibandronate injection (Boniva IV) is indicated for the treatment of osteoporosis in postmenopausal women.<sup>1</sup> Ibandronate is also available as a tablet formulation.<sup>2</sup>

### POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of ibandronate injection (Boniva IV). Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). 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.

### RECOMMENDED AUTHORIZATION CRITERIA

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

#### FDA-Approved Indications

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- 1. Osteoporosis Treatment for a Postmenopausal Patient.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A)** The patient meets ONE of the following conditions (i, ii, or iii):
    - i.** The 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.** The patient has had an osteoporotic fracture or a fragility fracture; OR
    - iii.** The patient has low bone mass (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]) and the physician determines that the patient is at high risk for fracture; AND
  - B)** The patient meets ONE of the following (i, ii, iii, or iv):
    - i.** The patient has tried one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
      - a)** The patient has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of BMD, lack of BMD increase); OR
      - b)** The patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy; OR
      - c)** The patient has experienced intolerability to an oral bisphosphonate (e.g., severe gastrointestinal [GI]-related adverse effects); OR
    - ii.** The patient cannot take an oral bisphosphonate due to one of the following circumstances: (a, b, or c):
      - a)** The patient cannot swallow or has difficulty swallowing; OR
      - b)** The patient cannot remain in an upright position post oral bisphosphonate administration; OR

- c) The patient has a pre-existing GI medical condition in which IV bisphosphonate therapy may be warranted (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]);  
OR
- iii. The patient has tried ibandronate injection (Boniva IV) or zoledronic acid injection (Reclast); OR
- iv. The patient has had an osteoporotic fracture or a fragility fracture.

**Dosing.** Approve 3 mg IV once every 3 months.

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#### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Ibandronate injection (Boniva IV) has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Osteoporosis Prevention.** Ibandronate injection (Boniva IV) is not indicated for the prevention of osteoporosis and supporting data are limited.
2. **Concurrent Use of ibandronate injection (Boniva IV) with Other Medications for Osteoporosis** (e.g., other bisphosphonates [previously listed], Prolia® [denosumab injection for subcutaneous use], Forteo® [teriparatide for subcutaneous {SC} use], Tymlos® [abaloparatide injection for SC use], calcitonin nasal spray), except calcium and Vitamin D.
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. Boniva® injection [prescribing information]. South San Francisco, CA: Genentech USA/Roche; December 2016.
2. Boniva® tablets [prescribing information]. South San Francisco, CA: Genentech USA/Roche; December 2016.

**HISTORY**

Type of Revision	Summary of Changes*	Approval Date
Annual revision	No criteria changes.	01/25/2017
Annual revision	<p>Changed the name of the policy to add “Bone Modifiers” – Boniva IV CC. Regarding osteoporosis treatment for a postmenopausal patient treatment of osteoporosis in men, regarding the T-score it was added to include 33% (one-third) radius (wrist) as a site. Also, a fragility fracture was added as an accepted manner to diagnose osteoporosis, in addition to an osteoporotic fracture. Also, regarding previous criteria that addressed patients with T-score at or below -2.0, the criteria were revised to state low bone mass (T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% [one-third] radius [wrist]) and the physician “determines” (instead of the word “believes”) that the patient is at high risk for fracture (the labs/diagnostic section was altered accordingly). Also, patients who were on oral bisphosphonate therapy and had a fragility fracture (in addition to the previously-cited osteoporotic fracture) are permitted to use either agent (in addition to meeting other criteria). Patients that have had an osteoporotic fracture or a fragility fracture are also granted exceptions as they are at higher risk. Evista (raloxifene tablets) was deleted from the list of osteoporosis medications in which Boniva IV should not be used with concurrently; Tymlos was added to this list.</p>	02/14/2018
Annual revision	<p>The name of the policy was changed from Bone Modifiers - Boniva IV to Bone Modifiers - Ibandronate IV (Boniva IV) to reflect availability of the product as a generic. The requirement to check renal function prior to each dose was removed.</p>	02/27/2019