VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Bone Modifiers – Ibandronate (Boniva) Intravenous Utilization Management Medical Policy

- Boniva® (ibandronate intravenous infusion – Genentech/Roche, generic)

REVIEW DATE: 03/09/2022

OVERVIEW

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

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. 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 Boniva 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 the following criteria (A and B):
   - **A)** Patient meets ONE of the following conditions (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 must meet 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, b, or c):
       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) and lack of a BMD increase.

b) Patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy; OR

c) 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 circumstances: (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 IV up to once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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

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.** Note: Examples of other medications for osteoporosis 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.

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® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech/Roche; January 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Osteoporosis Treatment for a Postmenopausal Patient.** The criteria that requires low bone mass had the definition moved from the criteria to a Note and the wording was changed from "prescribing physician" to "prescriber". For the criteria requiring a trial of one oral bisphosphonate, the criteria were changed to state "at least one" and examples of oral bisphosphonates were added to a Note. Wording for the criterion regarding inadequate response to an oral bisphosphonate was changed to "experienced inadequate efficacy" and "prescribing physician" was changed to "prescriber". Examples of inadequate efficacy to an oral bisphosphonate were moved from the criteria to a Note. Wording of the criterion regarding intolerability to an oral bisphosphonate was changed to "experienced significant intolerance". Examples of significant intolerance were moved from the criteria to a Note. For the criterion that addresses if the patient has a pre-existing gastrointestinal medical condition, examples were moved from the criteria to a Note. **Conditions Not Recommended for Approval:** For the notation cited regarding "Concurrent Use of Ibandronate Injection (Boniva IV) with Other Medications for Osteoporosis" the examples of medications were moved from the criteria to a Note; the medication list was revised. Also, the wording stating "except calcium and vitamin D" were removed.	03/03/2021
Annual Revision	No criteria changes.	03/09/2022