# Medical Policy:

## Boniva® (ibandronate) Intravenous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.136 | March 28, 2024 | |



## Definitions

Boniva injection is indicated for the treatment of osteoporosis in postmenopausal women.

## Length of Authorization

Coverage will be provided for 12 months and may be renewed.

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

- 3 billable units per 3 months

## Guideline

### I. INITIAL APPROVAL CRITERIA

***Boniva*** *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent*

*with the medical necessity criteria that follows:*

1. **Treatment of Osteoporosis**
   A. Patient is a postmenopausal woman; **AND**
   B. Patient has documented diagnosis of osteoporosis indicated by one or more of the following:
      i. Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA at the 33% (one-third) radius site; **OR**
      ii. T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; **OR**
      iii. T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
   C. Patient must be at a high risk for fracture *(high risk for fracture includes, but is not limited to one of the following: history of an osteoporotic fracture as an adult, parental history of hip fracture, low BMI, rheumatoid arthritis, alcohol intake (3 or more drinks per day), current smoking, or history of oral glucocorticoids ≥ 5mg/dl of prednisone (or equivalent) for > 3months ever.)*; **AND**
   D. Patient has a documented intolerance to, or treatment failure of, an oral bisphosphonate product for a minimum 12 month trial; **AND**
      *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).*
   E. Patient has a documented failure or intolerance of Reclast

**II. Renewal Criteria**

1. Patient continues to meet Initial Approval Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: hypocalcemia, anaphylaxis, renal toxicity, severe bone, joint, and/or muscle pain, atypical femur fracture, osteonecrosis of jaw (ONJ), etc.;* **AND**
3. Disease response as indicated by one or more of the following:
   A. Absence of fractures; **OR**
   B. Increase in bone mineral density compared to pretreatment baseline; **AND**
4. Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover [i.e., serum C-terminal crosslinking telopeptide (CTX)]; **AND**
   A. Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)

## Limitations/Exclusions

If the above criteria is met, authorization will be granted for 4 treatments (1 every three months) over one year.

1. Boniva is contraindicated in patients with the following condition: hypocalcemia
2. The safety and effectiveness of Boniva for the treatment of osteoporosis are based on clinical data of one year duration. 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.
3. 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), Tymlos (abaloparatide subcutaneous injection), and calcitonin nasal spray*

### Dosage/Administration

| Indication | Dose |
|---|---|
| Postmenopausal Osteoporosis | 3 mg intravenous infusion every 3 months (12 weeks) |

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J1740 | Injection, ibandronate, 1 mg, 1 billable unit = 1 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 00004-0191-xx | Boniva 3 mg/3 ml single use prefilled syringe |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| M80.00XA-M80.08XS | Age-related osteoporosis with current pathological fracture |
| M81.0 | Age-related osteoporosis without current pathological fracture |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 3/28/2024 | Annual Review: Initial Criteria: Treatment of Osteoporosis: Added: "Patient has documented diagnosis of osteoporosis indicated by one or more of the following: Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA at the 33% (one-third) radius site; OR T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; OR T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; AND<br>Patient must be at a high risk for fracture *(high risk for fracture includes, but is not limited to one of the following: history of an osteoporotic fracture as an adult, parental history of hip fracture, low BMI, rheumatoid arthritis, alcohol intake (3 or more drinks per day), current smoking, or history of oral glucocorticoids > 5mg/dl of prednisone (or equivalent) for > 3months ever."*<br>Added "for a minimum 12 month trial" to the Statement "Patient has a documented intolerance to, or treatment failure of an oral bisphosphonate product for a minimum 12 month trial" and added examples of oral bisphosphonate products.<br>Renewal Criteria: Added: " Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: hypocalcemia, anaphylaxis, renal toxicity, severe bone, joint, and/or muscle pain, atypical femur fracture, osteonecrosis of jaw (ONJ), etc.;* AND Disease response as indicated by one or more of the following: Absence of fractures; OR<br>Increase in bone mineral density compared to pretreatment baseline; AND<br>Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover [i.e., serum C-terminal crosslinking telopeptide (CTX)]; AND |

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| | | Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)<br>Limitations/Exclusions: Added: 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), Tymlos (abaloparatide subcutaneous injection), and calcitonin nasal spray* |
| EmblemHealth & ConnectiCare | 7/24/2023 | Annual Review: No criteria changes |
| EmblemHealth & ConnectiCare | 4/06/2022 | Transferred policy to new template |
| EmblemHealth & ConnectiCare | 04/16/2020 | Added the following to Limitations/Exclusions per FDA Label:<br>1. Boniva is contraindicated in patients with the following condition: hypocalcemia<br>2. The safety and effectiveness of Boniva for the treatment of osteoporosis are based on clinical data of one year duration. 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. |

## References


1. Boniva injection full prescribing information. Nutley, NJ. Roche Laboratories
2. National Osteoporosis Foundation (NOF). Physician's guide to prevention and treatment of osteoporosis. Washington, DC: NOF; 2003. Available at: http://www.nof.org/physguide/impact_and_overview.htm.