

Medical Policy:

Boniva® (ibandronate) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 $\geq 20\%$ or hip fracture $\geq 3\%$; **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 $\geq 5\text{mg/dl}$ of prednisone (or equivalent) for > 3 months 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	<p>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 \leq-2.5 and/or forearm DXA at the 33% (one-third) radius site; OR T-score \leq-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 \geq 20% or hip fracture \geq 3%; AND Patient must be at a high risk for fracture (<i>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.</i>"</p> <p>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.</p> <p>Renewal Criteria: Added: " Absence of unacceptable toxicity from the drug. <i>Examples of unacceptable toxicity include: hypocalcemia, anaphylaxis, renal toxicity, severe bone, joint, and/or muscle pain, atypical femur fracture, osteonecrosis of jaw (ONJ), etc.</i>; AND Disease response as indicated by one or more of the following: Absence of fractures; OR Increase in bone mineral density compared to pretreatment baseline; AND 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</p>

		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: Added: Concurrent Use of Ibandronate Injection (Boniva IV) with Other Medications for Osteoporosis. <i>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</i>
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: <ol style="list-style-type: none"> 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.

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.