Boniva® (ibandronate) IV
(Intravenous)

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I. Length of Authorization

Coverage will be provided for 12 months and may be renewed (unless otherwise specified).

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- 3 mg single-dose prefilled syringe once per 12 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 3 billable units every 12 weeks

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,15]

- Confirmation patient is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must have creatinine clearance ≥ 30 mL/min; **AND**

Treatment of women with postmenopausal osteoporosis † [1,8,10,11,13,15-17]

- Patient has a 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**
- Patient must be at a high risk for fracture**; **AND**

- Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, or ibandronate; **OR**
- Patient has a documented contraindication* or intolerance to oral bisphosphonates such as alendronate, risedronate, or ibandronate

***Note**: Patients discontinuing treatment with denosumab due to a reduction in fracture risk (i.e., no longer high or very high risk) require subsequent antiresorptive therapy in order to prevent accelerated bone mineral density loss and increase in fracture risk. Coverage is provided for **one year** for this use prior to temporary discontinuation of intravenous antiresorptive therapy.*

± Ineffective response is defined as one or more of the following: [11,13,15]
– Decrease in T-score in comparison with baseline T-score from DXA scan – Patient has a new fracture while on bisphosphonate therapy
**** High risk for fractures include, but are not limited to, one or more of the following: [11,15]**
– 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 – History of oral glucocorticoids ≥5 mg/d of prednisone (or equivalent) for >3 months (ever)
*** Examples of contraindications to oral bisphosphonate therapy include the following: [12]**
– Documented inability to sit or stand upright for at least 30 minutes – Documented pre-existing esophageal disorders such as achalasia, esophageal stricture, esophageal varices, or Barrett's esophagus – Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g., Roux-en-Y gastric bypass)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,8,10,13]

Coverage can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III ; **AND**
- 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
  - 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**

- 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)

V. Dosage/Administration [1]

Indication	Dose
Postmenopausal Osteoporosis	Administer 3 mg intravenously every 3 months (12 weeks)

VI. Billing Code/Availability Information

HCPCS Code:

- J1740 – Injection, ibandronate sodium, 1 mg; 1 mg = 1 billable unit

NDC:

- Boniva 3 mg/3 mL single-dose prefilled syringe: 00004-0191-xx*

**Generic formulation available from various manufacturers*

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	Description
M80.00XA-M80.08XS	Age-related osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD)Local Coverage Determinations (LCDs), and Local Coverage Articles may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): N	**NCD/LCD Document (s):** A57603
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57603&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 5,8	**NCD/LCD Document (s):** A56907
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56907&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 6, K	**NCD/LCD Document (s):** A52421
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52421&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC