Boniva® (ibandronate)

Last Review Date: April 16, 2020	Number: MG.MM.PH.136

Definition

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

Max Units (per dose and over time) [Medical Benefit]:

- 3 billable units per 3 months

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. Patient is a postmenopausal woman requiring treatment of osteoporosis
2. Patient has a documented intolerance to, or treatment failure of an oral bisphosphonate product
3. Patient has a documented failure or intolerance of Reclast

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.

II. RENEWAL CRITERIA

See initial approval criteria.

Dosage/Administration

Indication	Dose
Postmenopausal Osteoporosis	– 3 mg intravenous infusion over 15 to 30 seconds every 3 months

Applicable Procedure Codes

J1740	Injection, ibandronate, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

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

Applicable Diagnosis Codes

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

Revision History

04/16/2020	Added the following to Limitations/Exclusions per FDA Label: 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.