Department:	Pharmacy Management	**Original Approval:**	01/20/2016
Policy #:	PM138	**Last Approval:**	05/09/2019
Title:	Ibandronate (Boniva®)		
Approved By:	UM Pharmacy Subcommittee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Ibandronate (Boniva): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Labs/diagnostics - Medication list (current and past) to include start and end dates of previous trials for all bisphosphonate therapies -Initial/extended approval -Dosing and duration of therapy.

BACKGROUND

Ibandronate injection (Boniva IV) is indicated for the treatment of osteoporosis in postmenopausal women.[1] Ibandronate is also available as a tablet formulation.[2]

DEFINITIONS

None.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	***Step-utilization of Part D drugs not required.***

Coverage of Boniva injection is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Osteoporosis Treatment for a Postmenopausal Patient.**

Criteria. Approve for 1 year if the *patient meets the following criteria (A AND B)*.

- **A)** The patient meets ONE of the following conditions (i, ii, or iii):
  - **i.** The 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.** The patient has had an osteoporotic fracture or a fragility fracture; OR

iii. The patient has low bone mass (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]) and the physician determines that the patient is at high risk for fracture; AND

B) The patient meets ONE of the following (i, ii, iii, or iv):

i. The patient has tried one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):

a) The patient has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of BMD, lack of BMD increase); OR

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

c) The patient has experienced intolerability to an oral bisphosphonate (e.g., severe gastrointestinal (GI)-related adverse effects); OR

ii. The patient cannot take an oral bisphosphonate due to one of the following circumstances: (a, b, or c):

a) The patient cannot swallow or has difficulty swallowing; OR

b) The patient cannot remain in an upright position post oral bisphosphonate administration; OR

c) The patient has a pre-existing GI medical condition in which IV bisphosphonate therapy may be warranted (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]); OR

iii. The patient has tried ibandronate injection (Boniva IV) or zoledronic acid injection (Reclast); OR

iv. The patient has had an osteoporotic fracture or a fragility fracture.

Dosing. Approve 3 mg IV once every 3 months.

Conditions Not Recommended for Approval

Boniva injection has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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** (e.g., other bisphosphonates [previously listed], Prolia® [denosumab injection for subcutaneous use], Forteo® [teriparatide for subcutaneous {SC} use], Tymlos® [abaloparatide injection for SC use], calcitonin nasal spray), except calcium and Vitamin D.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References	1. Boniva® injection [prescribing information]. South San Francisco, CA: Genentech USA/Roche; December 2016. 2. Boniva® tablets [prescribing information]. South San Francisco, CA: Genentech USA/Roche; December 2016.	
CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☒ WAH	
	☒ IMC	
	☒ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
01/13/2016	New	Kelly Force; Yusuf Rashid, RPh
01/20/2016	Approval	MMLT
01/12/2017	No revisions	Fran McGaugh

01/13/2017	Approval	MMLT
07/24/2017	Criteria completely updated and revised	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
07/25/2017	Approved	MMLT
03/09/2018	Reassigned from UM153 to PM138	Cindy Bush
05/07/2018	Transferred to new template	Cindy Bush
06/12/2018	Revised	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee
04/15/2019	Revised	Jennifer Farley, PharmD
05/09/2019	Approval	UM Pharmacy Subcommittee

Appendix A: Cockcroft-Gault Equation for Estimating Creatinine Clearance

There are many different methods that can be used to calculate an estimated creatinine clearance (CrCl). The Cockcroft-Gault is one formula that provides an estimate of CrCl using serum creatinine. It is only for adults. This formula tends to overestimate CrCl in obese persons and to underestimate it in those who are lean. The Cockcroft-Gault equation for calculating CrCl is as follows:

CrCl in adults **(men)** = $\frac{\text{(140 minus age [in years] X weight [in kg])}}{\text{(72 X serum creatinine [in mg/dL])}}$

For women, multiple the above results by 0.85. The steps, for clarity, are as follows:

1) Subtract the patient's age in years from 140.
2) Multiple by the patient's weight in kg (if weight is in pounds, divide by 2.2 to get kg).
3) Multiple the patient's serum creatinine (in mg/dL) by 72.
4) Divide the total from 2) by the total from 3).
5) If the patient is female, take the total from 4) and multiple by 0.85.

For example, a man who is 55 years of age, who weighs 160 pounds (72.7 kg), and with a serum creatinine 0.9 mg/dL, would have a calculated creatinine clearance of 95 mL/minute. For a woman with these same values, her CrCl would be 81 mL/minute.