Medicare Advantage Medical Utilization Review Policy

Policy:	**Bone Modifiers – Ibandronate Intravenous Utilization Management Medical Policy** • Boniva® (ibandronate intravenous infusion – Genentech/Roche, generics)
Date Reviewed:	04/10/2023
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	NGS, J6: Wisconsin, Minnesota, Illinois NGS, JK: New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

OVERVIEW

Ibandronate injection is indicated for the treatment of **osteoporosis** in postmenopausal women.[1]

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of ibandronate injection. Approval is recommended for those who meet the conditions of coverage in the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-APPROVED INDICATION

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 must meet both of the following (a and b):
a. The patient has low bone mass; AND
Note: An example of low bone mass includes a 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).
b. Prescriber determines that the patient is at high risk for fracture; AND

B) The patient meets ONE of the following (i, ii, iii, iv or v):
i. The patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a or b):
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).
a. The patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR
Note: Examples of an inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
b. The patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
ii. The patient cannot tolerate an oral bisphosphonate; OR
Note: An example would be if the patient cannot swallow or has difficulty swallowing.
iii. The patient has a medical contraindication to oral bisphosphonate; OR
Note: Examples would be if the patient cannot remain in an upright position post oral bisphosphonate administration or if 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}].
iv. The patient has tried ibandronate injection (Boniva IV) or zoledronic acid injection (Reclast); OR
v. The patient has had an osteoporotic fracture or a fragility fracture.

Dosing: Approve 3 mg IV once every 3 months.

OTHER USES WITH SUPPORTIVE EVIDENCE

2. Senile Osteoporosis in Male Patients.[3]

Criteria.[2] Approve for 1 year if the patient meets ONE of the following criteria (A or B):
A. The patient cannot tolerate an oral bisphosphonate; OR
Note: An example would be if the patient cannot swallow or has difficulty swallowing.
B. The patient has a medical contraindication to oral bisphosphonate.
Examples would include if the patient cannot remain in an upright position post oral bisphosphonate administration or if 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}].

Dosing: Approve 2mg IV once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ibandronate injection is not recommended in the following situations:

1. **Osteoporosis Prevention.** Medicare coverage of preventative services is limited by statute and prevention of osteoporosis is not covered by Medicare.

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

REFERENCES

1. Boniva® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech/Roche; January 2022.
2. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article: Billing and Coding: Ibandronate Sodium (e.g., Boniva®) – Related to LCD L33394 (A52421) [original date 10/01/2015; revision effective date 10/01/2020]. Accessed on April 10, 2023.
3. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) [original date 10/01/2015; revision effective date 11/1/2022]. Accessed on April 10, 2023.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
Policy created	New Medicare Advantage Medical Policy	07/11/18
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Article A52421 and Bone Modifiers – Ibandronate IV (Boniva IV) Utilization Review Policy.	02/27/2019
Policy revision	Completion of 2019 monthly monitoring process in accordance with Local Coverage Determination L33394, Local Coverage Article A52421, and Bone Modifiers – Ibandronate IV (Boniva IV) Utilization Review Policy.	11/22/2019
Policy revision	Non-clinical update to policy to add the statement "This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage."	1/30/2020
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Determination L33394, Local Coverage Article A52421, and Bone Modifiers – Ibandronate IV (Boniva IV) Utilization Review Policy.	02/26/2020
Policy revision	*Added the following to the Policy Statement "Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage	08/10/2020

	Determinations, Local Coverage Determinations and/or Local Coverage Articles." *Updated references * Updated criteria for Osteoporosis Treatment for a Postmenopausal Patient: criteria added requiring T-score at or below -2.5, or previous fracture, or low bone mass in high risk patient. Criteria added allowing for coverage if patient has tried oral bisphosphonate with inadequate response, or tried Boniva IV or Reclast, or has had osteoporotic fracture or a fragility fracture	
Policy revision	**Osteoporosis Treatment for a Postmenopausal Patient.** The criteria that requires low bone mass had the definition moved from the criteria to a Note and the wording was changed from "prescribing physician" to "prescriber". For the criteria requiring a trial of one oral bisphosphonate, the criteria were changed to state "at least one bisphosphonate" and examples of oral bisphosphonates were added to a Note. Wording for the criterion regarding inadequate response to an oral bisphosphonate was changed to "experienced inadequate efficacy" and "prescribing physician" was changed to "prescriber". Examples of inadequate efficacy to an oral bisphosphonate were moved from the criteria to a Note. Wording of the criterion regarding intolerability to an oral bisphosphonate was changed to "experienced significant intolerance". Examples of significant intolerance were moved from the criteria to a Note. For the criterion that addresses if the patient has a pre-existing gastrointestinal medical condition, examples were moved from the criteria to a Note Removed "or oral bisphosphonate containing product" language throughout, terminology no longer used in Local Coverage Determination or Local Coverage Article	03/08/2021
Policy revision	The brand name of Boniva was removed from the title of the policy. **Osteoporosis – Treatment of a Postmenopausal Patient:** The requirement that the patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy was removed. Instead, this requirement was incorporated into a Note that lists osteoporotic fracture or a fragility fracture as an example of inadequate efficacy or significant intolerance to a trial of an oral bisphosphonate or an oral bisphosphonate-containing product.	04/10/2023