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RETIRED
Effective Date: 04/08/2021

Intravenous Bisphosphonates

Boniva® (ibandronate)

Reclast® (zoledronic acid)

Zometa® (zoledronic acid)

Aredia® (pamidronate disodium)

FDA approval: Various

HCPCS: Boniva - J1740; Zometa/Reclast - J3489; Aredia - J2430

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided for FDA approved indications and when all the following are met:
 - a. Boniva and Reclast:
 - i. For the treatment of one of the following:
 1. Glucocorticoid-induced osteoporosis
OR
 2. Osteoporosis in men
OR
 3. Postmenopausal osteoporosis (Confirmed by BMD T-score at or below -2.5 at the lumbar spine or total hip)
 4. Paget disease
 5. Documentation that an adequate trial of at least two oral bisphosphonates (such as generic alendronate) has been ineffective based on objective documentation, not tolerated despite taking it as recommended or is contraindicated
 - b. Zometa:
 - i. For the treatment of cancer-related indications:
 1. Bone metastases from solid tumors
 2. Hypercalcemia of malignancy
 3. Multiple myeloma
 - ii. Paget disease
 - c. Aredia:
 - i. For the treatment of cancer-related indications
 1. Hypercalcemia of malignancy
 2. Bone metastases from breast cancer

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- 3. Bone lesions of multiple myeloma
- ii. Paget disease

B. Quantity Limitations, Authorization Period and Renewal Criteria

- a. Authorization will be provided at 12 month intervals and may be reviewed at least annually to confirm that current medical necessity criteria are met.
- b. Boniva: One 3 mg infusion every 3 months
- c. Reclast: One 5 mg infusion per year
- d. Zometa:
 - i. Bone metastases from solid tumors, multiple myeloma
 - 1. Maximum of 4 mg every 4 weeks initially, may increase to every 3 weeks based on medical necessity
 - ii. Hypercalcemia of malignancy
 - 1. Maximum of 4 mg, retreatment may be authorized 7 days after the initial dose based on medical necessity
- e. Aredia:
 - i. Hypercalcemia of malignancy
 - 1. Maximum 90 mg over 2 to 24 hours, retreatment may be authorized 7 days after the initial dose based on medical necessity
 - ii. Bone metastases from breast cancer
 - 1. Maximum of 90 mg over 2 hours once every 3 to 4 weeks
 - iii. Bone lesions from multiple myeloma
 - 1. Maximum of 90 mg over 4 hours once monthly
 - iv. Paget disease
 - 1. Maximum 30 mg over 4 hours for 3 consecutive days

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication/Diagnosis

**Please refer to most recent prescribing information.*

<https://www.fda.gov/>

B. Background Information

- a. Pharmacologic therapies of choice in treating osteoporosis include a combination of adequate calcium and vitamin D intakes and bisphosphonates
- b. BMD increases with bisphosphonates are dose dependent and greatest in the first 6 to 12 months of therapy
- c. Weekly alendronate, weekly and monthly risedronate, and monthly oral and quarterly intravenous ibandronate therapy produce equivalent BMD changes to their respective daily regimens
- d. Annual intravenous zoledronic acid has documented both secondary fracture prevention and a decrease in mortality
- e. Moreover, additional benefits of bisphosphonate therapy include utilization to reduce pain and skeletal-related events and to improve quality of life.
- f. The FDA has provided indications for Zometa use in the following patient population:
 - i. Patients with bone metastases from solid tumors.

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- ii. Hypercalcemia of malignancy
- iii. Multiple myeloma

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

**Please refer to most recent prescribing information.*

F. How supplied

- a. Boniva: 3 mL syringe
- b. Reclast: 100 mL vial
- c. Zometa: 4 mg per 5 mL injection as a concentrated solution
- d. Aredia: 10 mL vial

References:

1. Boniva® [prescribing information]. Roche Laboratories Inc., Nutley, NJ. December 2016
2. Reclast® [prescribing information]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. July 2017.
3. Zometa® [prescribing information]. East Hanover, NJ: Novartis Pharma; December 2018.
4. Coleman RE, Marshall H, Cameron D, et al. Breast-Cancer Adjuvant Therapy with Zoledronic Acid. *N Eng J Med.* 2011; 365:1396-1405
5. Aredia® [prescribing information] East Hanover, NJ: Novartis Pharma; May 2012.

Policy History												
#	Date	Change Description										
1.9	Effective Date: 04/08/2021	Retiring policy as drug is not managed with prior authorization										
1.8	Effective Date: 4/16/2020	Annual Review										
1.7	Effective Date: 05/09/2019	Annual Review of Medical Policy										
1.6	Effective Date: 05/03/2018	Annual Review of Medical Policy										
1.5	Effective Date: 03/01/2018	PA removed for BCN from Boniva, Reclast, and Zometa <table border="1" data-bbox="451 577 1333 751"> <thead> <tr> <th>Line of Business</th> <th>PA Required (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>No</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	No	MAPPO	Yes	BCNA	Yes
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1.4	Effective Date: 07/05/2017	PA added for BCNA and MAPPO to Aredia, Boniva, Reclast, and Zometa <table border="1" data-bbox="451 840 1333 1014"> <thead> <tr> <th>Line of Business</th> <th>PA Required (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.3	Effective Date: 05/04/2017	Annual Review and template updated										
1.2	Effective Date: 05/05/2016	Updated Criteria with Aredia										
1.1	Effective Date: 08/2012	Criteria update										
1.0	Effective Date: 11/2011	New Policy. PA added for BCN for Boniva, Reclast, and Zometa <table border="1" data-bbox="451 1304 1333 1478"> <thead> <tr> <th>Line of Business</th> <th>PA Required (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.