Intravenous Bisphosphonates

Boniva® (ibandronate)
Reclast® (zoledronic acid)
Zometa® (zoledronic acid)
Aredia® (pamidronate disodium)

FDA approval: Various
Benefit: Medical

Policy/Criteria:

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

Coverage of the requested drug is provided for FDA approved indications and when all of the criteria are met. Coverage requests must be supported by submission of chart notes and patient specific documentation.

- Boniva and Reclast:
  - For the treatment of one of the following:
    - glucocorticoid-induced osteoporosis OR osteoporosis in men OR postmenopausal osteoporosis (Confirmed by BMD T-score at or below -2.5 at the lumbar spine or total hip)
    - Paget disease
  - 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.

- Zometa:
  - For the treatment of cancer-related indications:
    - Bone metastases from solid tumors
    - Hypercalcemia of malignancy
    - Multiple myeloma
  - Paget disease

- Aredia:
  - For the treatment of cancer-related indications
    - Hypercalcemia of malignancy
    - Bone metastases from breast cancer
    - Bone lesions of multiple myeloma
  - Paget disease

- Duration of coverage and Quantity Limits
  - Authorization will be provided at 12 month intervals and may be reviewed at least annually to confirm that current medical necessity criteria are met.
o Boniva: one 3 mg infusion every 3 months
o Reclast: one 5 mg infusion per year
o Zometa:

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<th>Indication</th>
<th>Dosage Description</th>
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<td>Bone metastases from solid tumors, multiple myeloma</td>
<td>Maximum of 4 mg every 4 weeks initially, may increase to every 3 weeks based on medical necessity</td>
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<tr>
<td>Hypercalcemia of malignancy</td>
<td>Maximum of 4 mg, retreatment may be authorized 7 days after the initial dose based on medical necessity</td>
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o Aredia:

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<th>Indication</th>
<th>Dosage Description</th>
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<td>Hypercalcemia of malignancy</td>
<td>Maximum 90 mg over 2 to 24 hours, retreatment may be authorized 7 days after the initial dose based on medical necessity</td>
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<td>Bone metastases from breast cancer</td>
<td>Maximum of 90 mg over 2 hours once every 3 to 4 weeks</td>
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<td>Bone lesions from multiple myeloma</td>
<td>Maximum of 90 mg over 4 hours once monthly</td>
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<td>Paget disease</td>
<td>Maximum 30 mg over 4 hours for 3 consecutive days</td>
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***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.

B. Background Information

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

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C. Efficacy

*Please refer to most recent prescribing information.

D. Medication Safety Considerations

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: Available as a 3 mL syringe
   b. Reclast: Available as 100 mL vial
   c. Zometa: Available as a 5 mL vial (4 mg per 5 mL injection is a concentrated solution and must be diluted prior to administration)
   d. Aredia: Available as 10 mL vial

References:

2. Reclast® [prescribing information]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. April 2016

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<th>Policy History</th>
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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