Reference number(s)
4367-A

Jurisdiction Specific Medicare Part B Bisphosphonate Drug Therapy

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
ibandronate sodium (brand unavailable)	ibandronate sodium	Intravenous (IV)
pamidronate disodium (all brands)	pamidronate disodium	Intravenous (IV)
zoledronic acid (all brands)	zoledronic acid	Intravenous (IV)

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Ibandronate Sodium IV

- Treatment of osteoporosis and osteopenia
- Hypercalcemia associated with malignancy
- Bone metastases secondary to solid tumors, breast cancer, prostate cancer
- Osteolytic lesions due to metastases
- Glucocorticoid-Induced Osteoporosis (GIOP) and Glucocorticoid-Induced Bone Loss in Transplant Recipients

Pamidronate Disodium IV

- Treatment of osteoporosis and osteopenia
- Hypercalcemia associated with malignancy

- Cancer Treatment-Induced Bone Loss (CTIBL) in Breast and Prostate Cancer
- Bone metastases secondary to solid tumors, breast cancer, and prostate cancer
- Multiple myeloma
- Osteolytic lesions due to metastases
- Paget's Disease of bone (osteitis deformans)
- Osteogenesis Imperfecta
- Fibrous dysplasia of bone (McCune-Albright syndrome)

Zoledronic Acid IV

- Treatment of osteoporosis and osteopenia
- Hypercalcemia associated with malignancy
- Cancer Treatment-Induced Bone Loss (CTIBL) in Breast and Prostate Cancer
- Bone metastases secondary to solid tumors, breast cancer, and prostate cancer
- Multiple myeloma
- Osteolytic lesions due to metastases
- Paget's Disease of bone (osteitis deformans)
- Discontinuation of Denosumab (Prolia/Xgeva) Therapy
- Glucocorticoid-Induced Osteoporosis (GIOP) and Glucocorticoid-Induced Bone Loss in Transplant Recipients

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Treatment of Osteoporosis and Osteopenia[1]

Authorization of 12 months may be granted for treatment of osteoporosis and osteopenia when any of the following criteria are met:

- The patient is a postmenopausal woman or man ≥ 50 years of age who has had a hip or vertebral fracture, including fragility fracture.
- The patient is a postmenopausal woman or man ≥ 50 years of age who has a bone mineral density value consistent with osteoporosis (i.e., T-scores equal to or worse than -2.5) at the lumbar spine, femoral neck, or total hip region.
- The patient is a postmenopausal woman or man ≥ 50 years of age with a T-score from -1.0 to -2.5 and any one of the following:
    - History of fracture of the proximal humerus, pelvis, or distal forearm
    - History of multiple fractures at other sites (excluding face, feet, and hands)
- Pharmacologic therapy is recommended in a patient with osteopenia and one of the following:
    - The patient's FRAX 10-year probability for major osteoporotic fracture is ≥ 20%.

- The patient's 10-year probability for hip fracture is ≥ 3%.

Hypercalcemia Associated with Malignancy[1]

Authorization of 2 months may be granted for treatment of moderate or severe hypercalcemia associated with malignancy with or without bone metastases in conjunction with hydration.

Cancer Treatment-Induced Bone Loss (CTIBL) in Breast and Prostate Cancer[1]

Authorization of 12 months may be granted for treatment of cancer treatment-induced bone loss (CTIBL) when all of the following are met:

- The patient has a diagnosis of breast or prostate cancer.
- The patient is receiving concurrent adjuvant hormone therapy, an aromatase inhibitor, or a gonadotropin-releasing hormone (GnRH) antagonist or agonist.
- The requested drug is for pamidronate disodium IV or zoledronic acid IV.

Bone Metastases Secondary to Solid Tumors, Breast Cancer, Prostate Cancer[1]

Authorization of 12 months may be granted for treatment of bone metastases secondary to solid tumors, breast cancer, prostate cancer.

Multiple Myeloma[1]

Authorization of 12 months may be granted for treatment of multiple myeloma if the requested drug is for pamidronate disodium IV or zoledronic acid IV.

Osteolytic Lesions Due to Metastases[1]

Authorization of 12 months may be granted for treatment of osteolytic lesions due to metastases.

Paget's Disease of Bone (osteitis deformans)[1]

Authorization of 1 month may be granted for treatment of moderate to severe Paget's disease of bone (osteitis deformans) when the requested drug is pamidronate disodium IV.

Authorization of 1 dose may be granted for the initial treatment of moderate to severe Paget's disease of bone when the requested drug is zoledronic acid and both of the following are met:

- The request is for a single treatment of zoledronic acid.
- The member meets any of the following:

- There is an elevation in serum alkaline phosphatase two times or higher than the upper limit of the age specific normal reference range.
- There is risk for complications from Paget's disease.
- The intent of treatment is to induce remission (normalization of serum alkaline phosphatase).

Authorization of 1 month may be granted for the treatment of moderate to severe Paget's disease of the bone when the requested drug is zoledronic acid and both of the following are met:

- The member has relapsed after one year of remission.
- Retreatment with zoledronic acid is considered reasonable and necessary due to any of the following:
  - There is an increase in serum alkaline phosphatase.
  - There is a failure to achieve normalization of alkaline phosphatase.
  - Retreatment is dictated by medical practice for symptom recurrence.

Osteogenesis Imperfecta[1]

Authorization of 12 months may be granted for treatment of osteogenesis imperfecta if the requested drug is for pamidronate disodium IV.

Fibrous Dysplasia of Bone (McCune-Albright syndrome)[1]

Authorization of 12 months may be granted for treatment of fibrous dysplasia of bone (McCune-Albright syndrome) if the requested drug is for pamidronate disodium IV.

Discontinuation of Denosumab (Prolia or Xgeva) Therapy[1]

Authorization of 12 months may be granted after discontinuing denosumab (Prolia/Xgeva) therapy if the requested drug is zoledronic acid IV.

Treatment or Prevention of Glucocorticoid-Induced Osteoporosis (GIOP) and Glucocorticoid-Induced Bone Loss in Transplant Recipients[1]

Authorization of 12 months may be granted for the treatment or prevention of glucocorticoid-induced osteoporosis (GIOP) or glucocorticoid-induced bone loss in transplant recipients when all of the following are met:

- The request is for treatment with ibandronate sodium IV or zoledronic acid IV.
- The patient meets one of the following:
  - The patient is taking glucocorticoids at any dose with an anticipated duration of ≥ 3 months and will maintain a total calcium intake of 1000 to 1200 mg/day and vitamin D intake of 600 to 800 international units (IU) per day through either diet and/or supplements.

- The patient is receiving high-dose glucocorticoids and is at a moderate, high, or very high risk of fracture.
- The patient is receiving high-dose glucocorticoids after undergoing a solid-organ transplant and all of the following are met:
    - The patient's glomerular filtration rate (GFR) is greater than 35 mL/min.
    - There is no evidence of chronic kidney disease-mineral and bone disorder (CKD-MBD).
    - There is no evidence of hyperparathyroidism.

References

1. Biphosphonate Drug Therapy LCD (L34648) Version R12. Available at: https://www.cms.gov/medicarecoverage-database/indexes/national-and-local-indexes.aspx. Accessed October 3, 2024.
2. Biphosphonate Drug Therapy LCA (A56907) Version R9. Available at: https://www.cms.gov/medicarecoverage-database/indexes/national-and-local-indexes.aspx. Accessed October 3, 2024.
3. Ibandronate sodium injection [package insert]. Weston, FL: Apotex Corp.; September 2022.
4. Pamidronate disodium injection. [package insert]. Lake Forest, IL: Hospira, Inc.; April 2021.
5. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
6. Zoledronic acid injection [package insert]. Morgantown, WV: Mylan Institutional LLC; January 2023.
7. Zometa [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.

