

Jurisdiction Specific Medicare Part B

Ibandronate

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 (brand unavailable)	ibandronate	injection

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.

- Postmenopausal osteoporosis
- Postmenopausal osteopenia
- Bone metastases from solid tumors or multiple myeloma
- Osteoporosis disorder related to transplantation
- Hypercalcemia of malignancy
- Paget's disease (osteitis deformans)
- Corticosteroid-induced osteoporosis
- Senile Osteoporosis in a male patient
- Compendial uses- ICD-10 codes supported by the Medicare Administrative Contractor

The list of covered ICD-10 codes is prohibitively long to include in within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

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

Postmenopausal Osteoporosis^{2,4}

Authorization of 12 months may be granted for treatment of postmenopausal osteoporosis when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Postmenopausal Osteopenia²

Authorization of 12 months may be granted for treatment of postmenopausal osteopenia when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Bone Metastases from a Solid Tumor or Multiple Myeloma^{2,5}

Authorization of 12 months may be granted for prevention of skeletal-related events in patients with bone metastases from a solid tumor or multiple myeloma when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Osteoporosis Related to Renal Transplantation^{2,5}

Authorization of 12 months may be granted for treatment of osteoporosis disorder related to renal transplantation when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Hypercalcemia of Malignancy²

Authorization of 2 months may be granted for treatment of hypercalcemia of malignancy when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Paget's Disease (osteitis deformans)²

Authorization of 1 month may be granted for treatment of Paget's disease (osteitis deformans) when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Corticosteroid-Induced Osteoporosis^{2,7}

Authorization of 12 months may be granted for treatment of corticosteroid-induced osteoporosis when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

Senile Osteoporosis in a Male Patient¹

Authorization of 12 months may be granted for treatment of senile osteoporosis in a male patient when bisphosphonate therapy is medically necessary and the patient cannot tolerate oral bisphosphonates or oral bisphosphonates are medically contraindicated.

All Other Indications¹⁻³

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52421.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 3, 2024.
2. Billing and Coding: Ibandronate Sodium (A52421) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 3, 2024.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 3, 2024.
4. Ibandronate sodium injection [package insert]. Weston, FL: Apotex Corp.; September 2022.
5. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed October 3, 2024.
6. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2020. <https://www.clinicalkey.com/pharmacology>. Accessed October 3, 2024.
7. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com>. Accessed October 3, 2024.