Zoledronic Acid (Zometa® & Reclast®)

Guideline Number: MPG357.10
Approval Date: February 23, 2024

➲ Terms and Conditions

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Related Medicare Advantage Reimbursement Policy

- Discarded Drugs and Biologicals Policy, Professional

Policy Summary

➲ See Purpose

Overview

Zoledronic acid (Reclast and Zometa) is a bisphosphonic acid, which is an inhibitor of osteoclastic bone resorption. Zoledronic acid binds to the bone matrix, which decreases osteoclastic activity, prevents bone resorption and skeletal calcium release induced by various stimulatory factors released by tumors. Zoledronic acid is currently available under the brand names Zometa and Reclast.

Zometa Guidelines

Zometa

- An indication that the patient is not on any other bisphosphonate medication(s).
- An indication that the renal status of the patient has been monitored.
- Retreatment with Zometa® 4 mg may be considered if serum calcium does not return to normal or remain normal after treatment.

Zometa for Hypercalcemia of Malignancy

- An indication that the patient has an albumin-corrected serum calcium of ≥ 12 mg/dL (3.0 mmol/L).

Zometa for Multiple Myeloma and Metastatic Bone Lesions of Solid Tumors

- An indication that the patient was coadministered oral calcium supplements of 500 mg and a multiple vitamin containing 400 IU of vitamin D per day.

Reclast Guidelines

Reclast® used for prevention without a confirmed diagnosis of osteoporosis in postmenopausal women will not be covered because it is not considered medically reasonable and necessary in the diagnosis and treatment of a specific illness or injury as defined in the Social Security Act, Section 1862(a)(1)(A) and as stated in CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50.4.

Reclast for Glucocorticoid-Induced Osteoporosis in Men and Women (must meet above criteria also)

- An indication that the patient is either initiating or continuing to take system glucocorticoids in a daily dosage of 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months.
- the patient is taking at least 1,200 mg calcium and 800-1,000 IU vitamin D per day.

Reclast for Women or Men with Osteoporosis

An indication that the patient is taking at least 1200 mg calcium and 800-1000 IU vitamin D per day.

Reclast for Paget's Disease

An indication that the patient has one of the following:

- An elevated serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or
- The patient is symptomatic, or
- The patient is at risk for complications from the disease, to induce remission (normalization of serum alkaline phosphotase) prior to treatment with Reclast.

Reclast for Re-Treatment of Paget's Disease

- An indication that the patient is experiencing a relapse based on serum alkaline phosphatase, or
- An indication that the patient has failed to achieve normalization of their serum alkaline phosphatase, or
- An indication that the patient has symptoms as dictated by current standard medical practice.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J3489	Injection, zoledronic acid, 1 mg

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L34648 Bisphosphonate Drug Therapy	A56907 Billing and Coding: Bisphosphonate Drug Therapy	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L33270 Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications	A57603 Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications	First Coast	FL, PR, VI	FL, PR, VI

CMS Benefit Policy Manual

Chapter 15, Section 50 Drugs and Biologicals, Sections 50.1 Definition of Drug or Biological, 50.2 Determining Self-Administration of Drug or Biological, 50.3 Incident To Requirements, 50.4 Reasonableness and Necessity, 50.4.1 Approved Use of Drug, 50.4.2 Unlabeled Use of Drug, and 50.4.3 Examples of Not Reasonable and Necessary

CMS Claims Processing Manual

Chapter 17, Section 10 Payment Rules for Drugs and Biologicals

Other(s)

Refer to the FDA drug label for the FDA approved indications and dosages for Reclast® and Zometa® at https://labels.fda.gov
About Zometa (Zoledronic Acid) 4 mg/5 mL Injection, Zometa Website
Medicare Program Integrity Manual, Chapter 3 Verifying Potential Errors and Taking Corrective Actions, CMS Website
Reclast (Zoledronic Acid), Novartis Pharmaceuticals Website

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
02/23/2024	**Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version MPG357.09

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section above to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing

Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.