

# Zoledronic Acid (Zometa® & Reclast®)

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[↪ Terms and Conditions](#)

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Related Medicare Advantage Policy Guideline
<ul style="list-style-type: none"> <li><a href="#">Coverage of Drugs and Biologicals for Label and Off-Label Uses</a></li> </ul>
Related Medicare Advantage Reimbursement Policy
<ul style="list-style-type: none"> <li><a href="#">Discarded Drugs and Biologicals Policy, Professional</a></li> </ul>

## 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 is indicated for the treatment of:

- Acute Hypercalcemia of malignancy;
- Multiple myeloma;
- Bone metastases from solid tumors in conjunction with standard antineoplastic therapy, including bone metastases from multiple myeloma, breast carcinoma, prostate carcinoma, and other solid tumors. Note: Prostate cancer should have progressed after treatment with at least one hormonal therapy;
- Drug-induced osteopenia, secondary to androgen-deprivation therapy in prostate cancer patients (prophylaxis); and
- Cancer treatment-induced bone loss in breast cancer.

Reclast is indicated for the treatment of:

- Pagets disease;
- Post-Menopausal (Senile) Osteoporosis;
- Osteoporosis in men; and
- Glucocorticoid - induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months

### 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

#### Zometa for Hypercalcemia of Malignancy

- An indication that the patient has an albumin-corrected serum calcium of  $\geq 12$  mg/dL (3.0 mmol/L)
- The date of the last treatment must be indicated

### ***Zometa for Multiple Myeloma and Metastatic Bone Lesions of Solid Tumors***

- An indication that for the patient with a creatinine clearance of > 60 mL/min, a 4 mg IV infusion over no less than 15 minutes was administered every 3-4 weeks by a healthcare provider
- 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 – All patients***

- An indication that the patient received adequate hydration prior to treatment
- An indication that the patient has a creatinine clearance of  $\geq 35$  mL/min or better

#### ***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

#### ***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 phosphatase) 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.

### **Utilization Guidelines**

#### ***Zometa***

- Zometa contains the same active ingredient found in Reclast. A patient that is already receiving Zometa should not be treated with Reclast.
- Renal function must be carefully monitored in all patients receiving Zometa and possible deterioration in renal function must be assessed prior to re-treatment with Zometa.

#### ***Reclast***

- Reclast contains the same active ingredient found in Zometa. A patient that is already receiving Zometa should not be treated with Reclast.
- Patients must receive adequate hydration prior to the administration of Reclast.
- For patients with creatinine clearance  $\geq 35$  mL/min the recommended dose of Reclast is 5 mg infused intravenously once a year over no less than 15 minutes given over a constant infusion rate with a 10 mL normal saline flush of the IV line following the infusion.

## 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
<a href="#">L34648 Bisphosphonate Drug Therapy</a>	<a href="#">A56907 Billing and Coding: Bisphosphonate Drug Therapy</a>	WPS	AK, AL, AR, AZ, CA (Entire State), CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO (Entire State), MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, KS, MO, NE, IN, MI
<a href="#">L33270 Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</a>	<a href="#">A57603 Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</a>	First Coast	FL, PR, VI	FL, PR, VI

### UnitedHealthcare Commercial Policy

[Maximum Dosage](#)

### Other(s)

[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
04/01/2021	<b>Template Update</b> <ul style="list-style-type: none"><li>Reformatted policy; transferred content to new template</li></ul>
08/12/2020	<b>Related Policies</b> <ul style="list-style-type: none"><li>Added reference link to the Medicare Advantage Policy Guideline titled <i>Coverage of Drugs and Biologicals for Label and Off-Label Uses</i></li></ul> <b>Supporting Information</b> <ul style="list-style-type: none"><li>Updated References section to reflect the most current information</li><li>Archived previous policy version MPG357.05</li></ul>

## 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 below 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.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

\*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](#).