

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Zometa Clinical Edit
<b>First Implementation Date:</b>	2003
<b>Proposed Date:</b>	June 16, 2022
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Zometa® (zoledronic acid)

**Why Issue Selected:** Zoledronic acid, marketed as Zometa® and Reclast®, is an injectable bisphosphonate first approved in 2001. It is a potent inhibitor of bone resorption and also displays some antitumor activity. Zoledronic acid products have different indications, and providers are advised to use caution to ensure the proper product and dosage are administered to patients. Zometa is FDA approved for the treatment of hypercalcemia of malignancy, for the treatment of bone metastasis associated with solid tumors, and for the treatment of multiple myeloma patients with documented osteolytic lesions; doses of Zometa should not exceed 4mg. Reclast is FDA approved for the treatment and prevention of osteoporosis in postmenopausal woman, osteoporosis in men, treatment and prevention of glucocorticoid-induced osteoporosis, and Paget disease of bone in men and women; doses of Reclast should not exceed 5mg. Zometa only will be reviewed in this edit; Reclast will be reviewed in the Parathyroid Hormone and Bone Resorption Suppression Related Agents Clinical Edit.

### Program-Specific Information:

Date Range FFS 4-1-2021 to 3-31-2022				
Drug	Claims	Spend	Avg Spend per Claim	
ZOLEDRONIC ACID 4 MG/5 ML VIAL	491	\$12,468.12	\$25.39	
ZOLEDRONIC ACID 4 MG/100 ML	137	\$8,686.76	\$63.41	

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Zometa® (zoledronic acid)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

## Approval Criteria

- Participant aged  $\geq 18$  years **AND**
- Dosage  $\leq 4$  mg per claim **AND**
- Documented diagnosis of cancer

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:


Progress Notes:  
Other:

X

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

1 year

## References

- RECLAST (zoledronic acid) injection [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; April 2020.
- Clinical Pharmacology. Zoledronic Acid. Accessed May 19, 2022.
- Facts & Comparisons. Zoledronic Acid Injection. Accessed May 19, 2022.