SmartPA Criteria Proposal

Drug/Drug Class:	Zometa Clinical Edit
First Implementation Date:	2003
Proposed Date:	September 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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 7-1-2019 to 6-30-2020			
Drug	**Claims**	**Spend**	**Avg spend per claim**
ZOMETA 4 MG/5 ML VIAL	476	$24,522.91	$51.51
ZOMETA 4 MG/100 ML	152	$1,809.45	$120.45

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 ≥ 18 years **AND**
- Dosage ≤ 4mg per claim **AND**
- Documented ~~**or inferred**~~ diagnosis of cancer

Denial Criteria

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

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

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

Default Approval Period

1 year

References

- ZOMETA (zoledronic acid) injection, [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2018.
- RECLAST (zoledronic acid) injection [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; April 2020.