SmartPA Criteria Proposal

Drug/Drug Class: Zometa® Clinical Edit
First Implementation Date: 2003
Revised Date: February 27, 2020
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ Existing Criteria

Executive Summary

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

Why was this Issue Selected: Zolendronic 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. Zolendronic 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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 1-1-2019 to 7-11-2019</th>
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<tbody>
<tr>
<td>ZOLEDRONIC ACID 4 MG/5 ML VIAL</td>
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<td>Claims</td>
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<td>32</td>
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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 for review: Zometa® (zoledronic acid)
- Age range: All appropriate MO HealthNet participants aged 18 years and older
Approval Criteria

- Documented diagnosis of cancer in the past 2 years **OR**
- Inferred diagnosis of cancer in the past year **AND**
- Participant age ≥ 18 years **AND**
- Dosage ≤ 4mg per claim

Denial Criteria

- Therapy will be denied if no approval criteria met

Required Documentation

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

Disposition of Edit

Denial: Exception code “682” (Clinical Edit)

References

- Zometa [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2016.