Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: **Zometa® (zoledronic acid) Clinical Edit**

Prepared for: **Missouri Medicaid**
Prepared by: **Heritage Information Systems, Inc.**

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Requires evidence of a FDA-approved indication for use.

Why was this Issue Selected: Zolendronic acid is an injectable biphosphonate product that is indicated for treatment of hypercalcemia of malignancy, and the treatment of bone lesions associated with multiple myeloma and bone metastases of solid tumors.

Program-specific information:

Drug	How Supplied	AWP
• Zometa® (zoledronic acid) Injection	*4mg/Vial Lypholized Powder*	*$953.61*

Setting & Population: Cancer Patients 18 years of age or older with Hypercalcemia.

Type of Criteria:

☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**

☒ **Appropriate Indications** ☐

Data Sources:

☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Prior authorization criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Prior authorization criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Setting & Population

- Drug class for review: Zometa® (zoledronic acid) Injection
- Age range: Adult patients ≥ 18 years
- Diagnosis: History of Cancer and Hypercalcemia of Malignancy

Approval Criteria

- Therapy will be approved for the following indications:

Approval Diagnoses

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Cancer	140-208	--	720 days	
Cancer (inferred)	--	Antineoplastics	365 days	

Denial Criteria

- Patient age < 18 years
- Daily dosage > 4mg/claim

Required Documentation

Laboratory results: ☐ Progress notes: ☐
MedWatch form: ☐ Other: ☐

Disposition of Edit

- **Denial:** Edit 682 “Clinical Edit”

References

1. USPDI, Micromedex, 2003.