

## Clinical Edit Criteria Proposal

Drug/Drug Class: **Klonopin Wafer® (clonazepam) Clinical Edit**

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

**New Criteria**

**Revision of Existing Criteria**

### Executive Summary

**Purpose:** Encourage the use of generic product in tablet form.

**Why was this Issue Selected:**

The Klonopin Wafer® is a branded drug product containing clonazepam and is designed to rapidly dissolve on the tongue, allowing patients to take the medication without water, anytime, anywhere. The product is approved for the treatment of panic disorder with or without agoraphobia in adults. Klonopin Wafer's® are available in five strengths (0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg). Generic forms of clonazepam are available in oral tablet strengths of 0.5 mg, 1 mg, and 2mg and at significant lower costs or therapy.

**Program-specific information:**

Drug	AWP
• Klonopin Wafer® 0.125mg	\$1.00
• Klonopin Wafer® 0.25mg	\$1.00
• Klonopin Wafer® 0.5mg	\$1.05
• Klonopin Wafer® 1 mg	\$1.20
• Klonopin Wafer® 2 mg	\$1.67
• clonazepam 0.5mg tablet	\$0.0666 MAC
• clonazepam 1 mg tablet	\$0.0584 MAC
• clonazepam 2 mg tablet	\$0.1394 MAC

**Setting & Population:** NA

**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. Clinical Edit criteria, which is different from prior authorization or prior approval programs, assist in the achievement of qualitative and economic goals related to health care resource utilization without placing the entire utilization of a drug in a PA status. Screening the use of certain medications on the basis of clinical appropriateness can reduce costs by requiring evidence of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit 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: Klonopin Wafer<sup>®</sup>
- Age range: All patients
- Diagnosis: NA

## Approval Criteria

- Prescription claim history of oral clonazepam/ Klonopin<sup>®</sup> tablets.

## Denial Criteria

- Lack of evidence of trial and failure to oral clonazepam tablets

## Required Documentation

Laboratory results:   
MedWatch form:

Progress notes:   
Other:

## Disposition of Edit

- **Denial:** Edit 682 "Clinical Edit"

## References

1. USPDI, Micromedex, 2003.
2. Solvay Pharmaceutical Press Release, May 12, 2003.

