Clinical Edit Criteria Proposal

Drug/Drug Class: **Xanax XR® (Alprazolam) 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, immediate-release product forms.

Why was this Issue Selected: Xanax XR® is a branded, sustained-release tablet form of alprazolam. The product is indicated for the treatment of panic disorder, with or without agoraphobia.

Program-specific information:

Drug	AWP
• Xanax XR 0.5mg Tablet	*$*
• Xanax XR 1mg Tablet	*$*
• Xanax XR 2mg Tablet	*$*
• Xanax XR 3mg Tablet	*$*
• Alprazolam 0.25mg Tablet	*$0.0526/Tablet*
• Alprazolam 0.5mg Tablet	*$0.0655/Tablet*
• Alprazolam 1mg Tablet	*$0.0714/Tablet*
• Alprazolam 2mg Tablet	*$0.1642/Tablet*

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: Xanax XR®
- Age range: All patients
- Diagnosis: NA

Approval Criteria

- Diagnosis of any of the anxiety state diagnoses listed below:

Condition	Submitted ICD-9 Diagnosis	History Date Range	Client Approval (Initials)
Anxiety State	300.00	2 years	
Panic Disorder	300.01	2 years	
Generalized Anxiety Disorder	300.02	2 years	
Other Anxiety States	300.09	2 years	
Agoraphobia with Panic Attacks	300.21	2 years	

- Prescription claim history of generic, short-acting alprazolam tablets.

Denial Criteria

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

Required Documentation

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

Disposition of Edit

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

References

1. USPDI, Micromedex, 2003.
2. FDA Approved Labeling for Xanax XR NDA 21-434