

## Clinical Edit Criteria Proposal

Drug/Drug Class: Equetro® Clinical Edit

Date: January 18, 2006

Prepared for:

Prepared by: Missouri Medicaid

**New Criteria**

**Revision of Existing Criteria**

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Equetro® (extended-release carbamazepine).

**Why was this Issue Selected:**

Equetro® is a branded drug product containing extended-release carbamazepine. This product is formulated with immediate-release, extended-release, and enteric coated beads combined in a specific ratio to facilitate twice daily dosing. Equetro® is approved for the treatment of acute manic and mixed episodes associated with Bipolar I Disorder. Equetro® is available in three strengths, 100mg, 200mg, and 300mg Mphase capsules. Generic forms of carbamazepine are available in oral tablet strengths of 100mg and 200mg, as well as brand name extended-release Tegretol in 100mg, 200mg, and 400mg. These alternate formulations are priced significantly lower than Equetro®.

Equetro® is roughly 4 times more expensive than the MAC'd oral generic carbamazepine product.

	<b>Drug</b>	<b>Dosage Form</b>	<b>Cost per Dosage Form</b>
<b>Program-specific information:</b>	• Carbamazepine	100mg tab	\$0.2311AWP
	• Carbamazepine	200mg tab	\$0.3017AWP
	• Tegretol®	100mg tab	\$0.3738AWP
	• Tegretol®	200mg tab	\$0.7121AWP
	• Tegretol-XR®	100mg tab	\$0.3566AWP
	• Tegretol-XR®	200mg tab	\$0.7121AWP
	• Tegretol-XR®	400mg tab	\$1.4233AWP
	• Equetro®	100mg tab	\$1.2752AWP
	• Equetro®	200mg tab	\$1.2752AWP
	• Equetro®	300mg tab	\$1.2752AWP

**Setting & Population:** All patients.

**Type of Criteria:**  Increased risk of ADE  Non-Preferred Agent  
 Appropriate Indications

**Data Sources:**  Only administrative databases  Databases + Prescriber-supplied

## Setting & Population

- Drug for review: Equetro® (extended-release carbamazepine)
- Age range: All ages
- Gender: Male and female

## Approval Criteria

- Diagnosis of acute manic or mixed episodes associated with Bipolar I Disorder
- Initial stabilization/use of carbamazepine in the past 45 days.

## Denial Criteria

- Failure to meet approval criteria.

## References

1. Shire US Inc., "Equetro Formulary Kit," Wayne, Pennsylvania 19087. July 2005.
2. Facts and Comparisons, p.1017 - 1021. 2005.
3. USPDI, Micromedex, 2005.

