



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Equetro Clinical Edit
<b>First Implementation Date:</b>	January 18, 2006
<b>Revised Date:</b>	February 18, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

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

**Why Issue Selected:** Equetro® is an extended-release carbamazepine product formulated with immediate-release, extended-release, and enteric coated beads combined in a specific ratio to facilitate twice daily dosing. Other forms of extended release carbamazepine include Tegretol®-XR and Carbatrol®, both are formulated for twice daily dosing, available generically, and are approved for use as an anticonvulsant and for treatment of pain associated with trigeminal neuralgia. Equetro is currently only available as a brand name product; it also is approved for use as an anticonvulsant and for treatment of pain associated with trigeminal neuralgia, but also has an indication for the treatment of acute manic or mixed episodes associated with bipolar I disorder which other extended release carbamazepine agents lack. Equetro is available in three strengths, 100mg, 200mg, and 300mg capsules. Generic Tegretol-XR is available in 100, 200, and 400mg tablets. Generic Carbatrol is available in 100, 200, and 300mg capsules. Equetro is roughly 3 - 6 times more expensive than the generic extended release carbamazepine products.

**Program-Specific Information:**

Date Range FFS 7-1-2019 to 6-30-2020			
Drug	Claims	Spend	Cost per capsule
EQUETRO 100 MG CAPSULE	3	\$738.30	\$3.86 WAC
EQUETRO 200 MG CAPSULE	72	\$21,595.82	\$4.35 WAC
EQUETRO 300 MG CAPSULE	67	\$30,206.96	\$4.89 WAC

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug for review: Equetro® (extended-release carbamazepine)
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Documented diagnosis of acute manic or mixed episodes associated with bipolar I disorder **AND**
- Documented trial of another carbamazepine agent in the past 45 days

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:


Progress Notes:  
Other:

<b>X</b>

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

1 year

## References

- EQUETRO® [package insert]. Parsippany, NJ: Validus Pharmaceuticals LLC; October 2016
- TEGRETOL® and TEGRETOL®-XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
- CARBATOL® [package insert]. Lexington, MA: Shire US Inc.; September 2018.

### *SmartPA Clinical Proposal Form*

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