SmartPA Criteria Proposal

Drug/Drug Class:	Equetro Clinical Edit
First Implementation Date:	January 18, 2006
Proposed Date:	September 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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:		Progress Notes:	
MedWatch Form:		Other:	X

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.