SmartPA Criteria

Drug/Drug Class:  Equetro® Clinical Edit
First Implementation Date:  January 18, 2006
Proposed Date:  June 20, 2019
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 was this 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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 1-1-2018 to 12-31-2018</th>
<th>Claims</th>
<th>Spend</th>
<th>WAC/MAC per unit</th>
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</thead>
<tbody>
<tr>
<td>EQUETRO 100 MG CAPSULE</td>
<td></td>
<td>25</td>
<td>$2,916.51</td>
<td>3.86 WAC</td>
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<tr>
<td>EQUETRO 200 MG CAPSULE</td>
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<td>273</td>
<td>$43,076.00</td>
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<td>EQUETRO 300 MG CAPSULE</td>
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<td>$31,031.90</td>
<td>4.89 WAC</td>
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<td>TOTALS</td>
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<td>444</td>
<td>$77,024.40</td>
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<tr>
<td>CARBAMAZEPINE ER 100 MG CAP</td>
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<td>TOTALS</td>
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<td>13,529</td>
<td>$967,092.64</td>
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</table>
**Type of criteria:**
- [ ] Increased risk of ADE
- [x] Preferred Drug List
- [ ] Appropriate Indications
- [x] Clinical Edit

**Data sources:**
- [ ] Only administrative databases
- [x] Databases + Prescriber-supplied

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**Setting & Population**

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

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**Approval Criteria**

- Documented diagnosis of acute manic or mixed episodes associated with bipolar I disorder in the past 2 years
- Documented use of another carbamazepine agent in the past 45 days

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**Denial Criteria**

- Therapy will be denied if approval criteria are not met

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**Required Documentation**

- Laboratory Results: 
- MedWatch Form: 
- Progress Notes: 
- Other: X

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**Disposition of Edit**

Denial: Exception code “682” (Clinical Edit)

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**References**

2. TEGRETOL® and TEGRETOL®-XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2018