MEDICATION POLICY

Generic Name: Tolcapone

Therapeutic Class or Brand Name: Tasmar®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Tolcapone (generic)

Non-Preferred: Tasmar®

Date of Origin: 2/7/16 **Date Last Reviewed/Revised:** 7/18/17

GPI Code: 7315207000

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI are met):

I. Documented diagnosis of Parkinson's disease AND criterion A is met:
   A. Documentation that patient is experiencing symptom fluctuations.
II. Documentation that the patient is taking AND will continue to take levodopa/carbidopa in addition to tolcapone.
III. Documented trial and failure of entacapone.
IV. Minimum age requirement: 18 years old.
V. Prescriber must be a neurologist.
VI. Non-preferred products (i.e. Tasmar®) require a documented clinical reason containing details as to why generic tolcapone is not appropriate or is contraindicated.

Exclusion Criteria:

- Patients with liver disease or two SGPT/ALT or SGOT/AST values greater than the upper limit of normal.
- Patients who were withdrawn from tolcapone because of evidence of tolcapone-induced hepatocellular injury.
- Patients with a history of nontraumatic rhabdomyolysis or hyperpyrexia and confusion possibly related to medication.
- Concomitant use of tolcapone with a non-selective MAO inhibitor (i.e. phenelzine, tranylcypromine, etc.).

Other Criteria:

- Tolcapone should be discontinued in patients who do not show substantial clinical benefit within 3 weeks of initiation of treatment.

Quantity/Days Supply Restrictions:

- Up to a maximum of 180 tablets per 30 days.

Approval Length:

- **Authorization:** 1 month.
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met, the medication is effective, and patient's liver function is normal.

Appendix:

N/A

References:

1. http://www.valeant.com/Portals/25/Pdf/PI/Tasmar_2015.pdf.
2. Medi-Span.
3. https://network-health.org/uploadedFiles/pdfs/medication_necessity_guidelines/tolcapone.en.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
7/18/2017	1. **Changed** "N/A" **to** "Preferred: Tolcapone (generic); Non-Preferred: Tasmar®" **under Applicable Drugs**. 2. **Added** "VI. Non-preferred products (i.e. Tasmar®) require a documented clinical reason containing details as to why generic tolcapone is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 3. **Removed** "https://www.pbmplus.com/memberportal/pacriteria.pdf" **under References** (link no longer valid).