

Generic Name: Tolcapone Therapeutic Class or Brand Name: Tasmar Applicable Drugs (if Therapeutic Class): N/A Preferred: Tolcapone (generic) Non-preferred: Tasmar Date of Origin: 2/7/2016 Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

- I. Documented diagnosis of Parkinson's disease and both criteria A and B are met:
 - A. Documentation that patient is currently taking levodopa/carbidopa.
 - B. Documentation that patient is experiencing symptom fluctuations.
- II. Documented treatment failure or contraindication to entacapone.
- III. Tolcapone will be used in combination with levodopa/carbidopa.
- IV. Minimum age requirement: 18 years old.
- V. Treatment is prescribed by or in consultation with a neurologist.
- VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

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- Patients who were withdrawn from tolcapone because of evidence of tolcapone-induced hepatocellular injury.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 (ie, phenelzine, tranylcypromine, etc.).

OTHER CRITERIA

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 Tolcapone should be discontinued in patients who do not show substantial clinical benefit as indicated by improved motor function and activities of daily living (ADL) 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 with sustained clinical benefit as indicated by improved motor function and ADL, and patient's liver function is normal.

APPENDIX

• N/A

REFERENCES

- Liang TW, Tarsy D. Medical management of motor fluctuations and dyskinesia in Parkinson disease. In: Hurtig H, ed. UpToDate. UpToDate; 2024. Accessed September 27, 2024. <u>https://www.uptodate.com/contents/medical-management-of-motor-fluctuations-anddyskinesia-in-parkinsondisease?search=tolcapone%20place%20in%20therapy&source=search_result&selectedTitle=2~ 150&usage_type=default&display_rank=2#H4
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- Tasmar. Prescribing information. Legacy Pharmaceuticals Puerto Rico, LLC; 2013. Accessed September 27, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020697s004lbl.pdf

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.