

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Tolcapone Products Prior Authorization Policy

- Tasmar® (tolcapone tablets, generics [100 mg strength only])

REVIEW DATE: 08/19/2020

OVERVIEW

Tolcapone, an inhibitor of catechol-O-methyltransferase, is used in the treatment of Parkinson's disease as an adjunct to levodopa/carbidopa therapy.¹

Guidelines

The American Academy of Neurology published guidelines in 2006 on the treatment of Parkinson's disease with motor fluctuations and dyskinesia.² The guidelines are dated and do not include more recently approved medications. It is recommended to offer entacapone and rasagiline to reduce "off" time (Level A). Pergolide (withdrawn from the market in 2007 due to risk of valvular fibrosis), pramipexole, ropinirole, and tolcapone (used with caution; requires monitoring for hepatotoxicity) should be considered to reduce "off" time (Level B). Apokyn® (apomorphine hydrochloride injection), cabergoline, and selegiline may be used to reduce "off" time (Level C). According to the guidelines, the available evidence does not establish superiority of one medication over another in reducing "off" time (Level B). Sustained-release levodopa/carbidopa and bromocriptine should not be considered to reduce "off" time (Level C). Amantadine may be used to reduce dyskinesia (Level C).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of tolcapone products. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with tolcapone products as well as the monitoring required for adverse events and long-term efficacy, approval requires tolcapone products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of tolcapone products is recommended in those who meet the following criteria:

FDA-Approved Indications

- 1. Parkinson's Disease.** Approve for 1 year if the patient meets all of the following criteria (A, B, and C):
 - A)** Patient is currently receiving carbidopa/levodopa therapy; **AND**
 - B)** Patient has tried an entacapone product and meets **ONE** of the following criteria (i or ii):
 - i.** Patient had significant intolerance, according to the prescriber; **OR**
 - ii.** Patient had inadequate efficacy, according to the prescriber; **AND**
 - C)** Tolcapone is being prescribed by, or in consultation with, a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of tolcapone products is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tasmar[®] oral tablets [prescribing information] Bridgewater, NJ: Valeant Pharmaceuticals; December 2018.
2. Pahwa R, Factor SA, Lyons KE, et al. Practice parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the quality standards subcommittee of the American Academy of Neurology. *Neurology*. 2006;66:983-995.