

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Tolcapone Prior Authorization Policy

- Tasmar[®] (tolcapone tablets – Bausch Health, generic)

REVIEW DATE: 09/14/2022

OVERVIEW

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

Safety

Tolcapone has a Boxed Warning of the risk of potentially fatal, acute fulminant liver failure and should be reserved for patients who are experiencing symptom fluctuations and are not responding satisfactorily to or are not appropriate candidates for other adjunctive therapies.¹

Guidelines

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).² The review categorically divides treatment recommendations by Parkinson's disease characteristics. Tolcapone and entacapone, another COMT inhibitor, are noted to be efficacious and possibly useful for treatment of motor fluctuations.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of tolcapone. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with tolcapone as well as the monitoring required for adverse events and long-term efficacy, approval requires tolcapone 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 is recommended in those who meet the following criteria:

FDA-Approved Indication

- 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

09/14/2022

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Coverage of tolcapone 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. Tasmal[®] tablets [prescribing information] Bridgewater, NJ: Bausch Health; October 2020.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord.* 2018;33(8):1248-1266.