

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Tolcapone Prior Authorization Policy

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

REVIEW DATE: 03/13/2024

OVERVIEW

Tolcapone, a catechol-O-methyltransferase (COMT) inhibitor, is indicated as an adjunct to levodopa and carbidopa for the treatment of signs and symptoms of idiopathic **Parkinson's disease**.¹

Safety

Tolcapone has a Boxed Warning regarding the risk of potentially fatal, acute fulminant liver failure and use 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.

The Academy of Family Physicians published recommendations for practice for the treatment of Parkinson's Disease (2020).³ The review recommends that tolcapone use should be limited due to the risks associated with fulminant hepatic failure.

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 (A, B, and C):
 - A)** Patient is currently receiving carbidopa/levodopa therapy; **AND**
 - B)** Patient has tried an entacapone product or Ongentys (opicapone capsules) and meets **ONE** of the following (i or ii):
 - i.** Patient had significant intolerance, according to the prescriber; **OR**
 - ii.** Patient had inadequate efficacy, according to the prescriber; **AND**

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- C) The medication is prescribed by or in consultation with a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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.
3. Halli-Tierney AD, Luker J and Carroll DG. Parkinson Disease. *Am Fam Physicians.* 2020;102(11):679-691.