

**TASMAR*
(tolcapone)**

* Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

RATIONALE FOR INCLUSION IN PA PROGRAM**Background**

Tasmar (tolcapone) is a selective and reversible inhibitor of catechol-O-methyltransferase (COMT). Tolcapone is thought to work by inhibiting COMT and altering the plasma pharmacokinetics of levodopa. When tolcapone is given in conjunction with levodopa and an aromatic amino acid decarboxylase inhibitor, such as carbidopa, plasma levels of levodopa are more sustained than after administration of levodopa and an aromatic amino acid decarboxylase inhibitor alone. These sustained plasma levels of levodopa result in more constant dopaminergic stimulation in the brain, leading to greater effects on the signs and symptoms of Parkinson's disease (1).

Regulatory Status

FDA-approved indications: Tasmar is indicated as an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson's disease (1).

Tasmar has a boxed warning regarding liver failure. Tasmar therapy should not be initiated if the patient exhibits clinical evidence of liver disease or two SGPT/ALT or SGOT/AST values greater than the upper limit of normal. Patients with severe dyskinesia or dystonia should be treated with caution. Tasmar should be discontinued if SGPT/ALT or SGOT/AST levels exceed 2 times the upper limit of normal or if clinical signs and symptoms suggest onset of hepatic dysfunction (1).

Because of the risk of potentially fatal, acute fulminant liver failure, Tasmar should ordinarily be used in patients with Parkinson's disease on l-dopa/carbidopa who are experiencing symptom fluctuations and are not responding satisfactorily to or are not appropriate candidates for other adjunctive therapies (1).

Because of the risk of liver injury and because Tasmar, when it is effective, provides an observable symptomatic benefit, the patient who fails to show substantial clinical benefit within 3 weeks of initiation of treatment, should be withdrawn from Tasmar (1).

The safety and effectiveness of Tasmar in pediatric patients less than 18 years of age have not



Federal Employee Program.

TASMAR* (tolcapone)

* Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

been established (1).

Summary

Tasmar (tolcapone) is used to treat the signs and symptoms of Parkinson's disease. Tasmar should be used in combination with levodopa and carbidopa. Patients taking Tasmar should have their liver function monitored. The safety and effectiveness of Tasmar in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Tasmar while maintaining optimal therapeutic outcomes.

References

1. Tasmar [package Insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.