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5.60.042

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 10, 2020
Subject:	Tasmar	**Page:**	1 of 5

Last Review Date: December 8, 2023

Tasmar

Description

Tasmar* (tolcapone)

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

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 indication: 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the patient who fails to show substantial clinical benefit within 3 weeks of initiation of treatment, should be withdrawn from Tasmar (1).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 been established (1).

Related policies
Inbrija, Nourianz, Nuplazid

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tasmar may be considered **medically necessary** if the conditions indicated below are met.

Tasmar may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Parkinson's disease

AND ALL of the following:

1. Used in combination with carbidopa/levodopa
2. Inadequate control of Parkinson's symptoms on maximum tolerated doses of oral carbidopa/levodopa therapy

3. Inadequate response, intolerance, or contraindication to other adjunctive therapy
4. Prescriber agrees to monitor for liver failure/hepatic dysfunction
5. Prescriber agrees to discontinue Tasmar (tolcapone) if ALT or AST levels exceed 2 times the upper limit of normal

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Parkinson's disease

AND ALL of the following:

1. Improvement in Parkinson's symptoms
2. Used in combination with carbidopa/levodopa
3. Prescriber agrees to monitor for liver failure/hepatic dysfunction
4. Prescriber agrees to discontinue Tasmar (tolcapone) if ALT or AST levels exceed 2 times the upper limit of normal

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Drug	Quantity
Tolcapone	270 tablets per 90 days

Drug with approved MFE only	Quantity
Tasmar	270 tablets per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

Drug	Quantity
Tolcapone	270 tablets per 90 days

Drug with approved MFE only	Quantity
Tasmar	270 tablets per 90 days

Duration 12 months

Rationale

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.

Policy History

Date	Action
January 2020	Addition to PA
March 2020	Annual review
December 2021	Annual editorial review and reference update
December 2022	Annual review. Changed policy number to 5.60.042
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.