UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2234-4
Program	Prior Authorization/Medical Necessity
Medication	Tasmar® (tolcapone)
P&T Approval Date	3/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Tasmar (tolcapone) is catechol-O-methyltransferase (COMT) inhibitor indicated as an adjunct to levodopa/carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson's Disease. Due to the of the risk of liver failure, Tasmar (tolcapone) should be used in patients with Parkinson's disease treated with levodopa/carbidopa who are experiencing symptom fluctuations and are not responding to or are not appropriate candidates for other adjunctive therapies. A patient who fails to show substantial clinical benefit within 3 weeks of initiation of treatment should be withdrawn from Tasmar therapy due to the risk of liver failure.

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Tasmar** will be approved based on **all** of the following criteria:

   a. Diagnosis of Parkinson's disease

   -AND-

   b. Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

   -AND-

   c. History of failure, contraindication, or intolerance to **all** of the following anti-Parkinson's disease adjunctive pharmacotherapy classes (trial must be from **all** of the different classes):

      1) Dopamine agonists (e.g., pramipexole, ropinirole)
      2) Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
      3) Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

   -AND-

   d. Patient has received baseline liver function tests to rule out the presence of underlying liver disease

-AND-

e. Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

-AND-

f. Prescriber attests they have had complete discussion with the patient about the risks and benefits of Tasmar use, including the risk of liver failure

Authorization will be issued for 3 months.

B. Reauthorization

1. **Tasmar** will be approved based on the following criterion:

   a. Documentation of positive clinical response to **Tasmar** therapy

   -AND-

   b. Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

   -AND-

   c. Patient has received periodic evaluation of liver function tests to rule out liver failure associated with Tasmar use

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Tasmar [package insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.
2. Fox, SH, Katzenschlager, R, Lim S, et. al. International Parkinson and Movement Disorder Society Evidence-Based Medicine Review: Update on Treatments for the Motor Symptoms of Parkinson's Disease. Movement Disorders. 2018.

Program	Prior Authorization/Medical Necessity – Tasmar (tolcapone)
Change Control	
3/2021	New program.
3/2022	Annual review. No changes.
3/2023	Annual review. No changes.