PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Tolcapone Prior Authorization Policy
- Tasmar® (tolcapone tablets – Bausch Health, generic)

REVIEW DATE: 03/12/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 of 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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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.** According to the prescriber, patient had significant intolerance; OR
     - **ii.** According to the prescriber, patient had inadequate efficacy; AND
   - **C)** The medication is prescribed by or in consultation with a neurologist.

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Tasmar® 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/20/2023
Early Annual Revision	**Parkinson's Disease:** The requirement that the patient has tried an entacapone product was changed to the patient has tried an entacapone product or Ongentys (opicapone capsules).	03/13/2024

Annual Revision	No criteria changes.	03/12/2025

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