Pharmacy Medical Necessity Guidelines: COMT Inhibitors

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Ongentys (opicapone) is a catechol-O-methyltransferase (COMT) inhibitors indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

Tolcapone is another COMT inhibitor indicated as an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic PD.

Because of the risk of potentially fatal, acute fulminant liver failure, tolcapone should ordinarily be used in patients with PD on l-dopa/carbidopa who are experiencing symptom fluctuations and are not responding satisfactorily to or are not appropriate candidates for other adjunctive therapies. Because of the risk of liver injury, the patient who fails to show substantial clinical benefit within 3 weeks of initiation of treatment should stop taking tolcapone.

The COMT inhibitor entacapone is also indicated as adjunct to levodopa and carbidopa to treat end-of-dose "wearing off" in patients with PD. Entacapone is the preferred COMT inhibitor for Tufts Health RITogether.

COVERAGE GUIDELINES

The plan may authorize coverage of **tolcapone** or **Ongentys** for Members when **ALL** of the following criteria for a particular regimen are met and limitations do not apply:

1. The Member is diagnosed with Parkinson's disease

AND

2. The Member will be taking the requested product concurrently with levodopa/carbidopa

AND

3. The Member has had an inadequate response, adverse reaction, or contraindication to therapy with the preferred catechol-o-methyltransferase (COMT) inhibitor agent, entacapone

LIMITATIONS

1. The quantity of tolcapone is limited to six tablets per day.
2. The quantity of Ongentys is limited to one tablet per day.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria

CODES

None

REFERENCES

1. Comtan (entacapone) [prescribing information]. Morristown, NJ: Almatica; May 2020.
2. Ongentys (opicapone) [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.
3. Tasmar (tolcapone) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: No changes.
2. March 12, 2024: Effective June 1, 2024, updated the previous trial language. Updated the fax number for RxUM.

3. March 11, 2025: No changes
4. March 10, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services