Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Rytary (carbidopa & levodopa ER) Step Therapy

Effective: January 13, 2026

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Rytary (carbidopa/levodopa extended-release capsule) is a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid) indicated for the treatment of Parkinson's disease, post-encephalitic Parkinsonism, and Parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of sale. If the patient does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan for patient who do not meet the step therapy criteria at the point of service.

Please refer to the table below for medications subject to this policy:

Drug	
Step-1	
carbidopa & levodopa ER capsules	Covered
carbidopa & levodopa ER tablets	
carbidopa & levodopa tablets	
carbidopa & levodopa ODT tablets	
Step-2	
Rytary capsules	Requires prior use of one (1) Step-1 drug (including one generic immediate release or one generic extended-release product)

Automated Step Therapy Coverage Criteria

The following stepped approach applies to **Rytary capsules** coverage by the plan:

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

a. The patient has had a trial with one of the following Step-1 medications within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan:

i. generic immediate-release carbidopa/levodopa

OR

ii. generic extended-release carbidopa/levodopa

Coverage Criteria for Patients Not Meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to Step-2 medications covered by the plan:

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

a. The patient has had a trial with one of the following Step-1 medications within the previous 180 days as evidenced by physician's documented use, excluding the use of samples:

i. generic immediate-release carbidopa/levodopa

OR

ii. generic extended-release carbidopa/levodopa

OR

b. The patient has a physician documented contraindication or intolerance to ONE Step-1 medication

Limitations

- Medications on Step-2 are not covered unless the above step therapy criteria are met.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- Step therapy point of service coding does not apply to any non-formulary medications.
- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Drugs for Parkinson's disease. Med Lett Drugs Ther 2017; 59:187.
2. Liang, TW, Tarsy D. Medical management of motor fluctuations and dyskinesia in Parkinson's disease. In: Eichler AF, ed. UpToDate [database online]. Waltham, MA: UpToDate, 2021. Accessed June 29, 2021.
3. Rytary (carbidopa/levodopa) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; December 2019.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 2022 P&T evote: Updated number of step requirements.
- August 8, 2023: No change
- November 12, 2024: No change
- January 13, 2026: No changes
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

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.