MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	**Carbidopa-Levodopa (Oral)** **Step Therapy Policy** • Crexont® (carbidopa-levodopa extended-release capsule – Amneal) • Rytary® (carbidopa-levodopa extended-release capsule – Amneal)	**Annual Review Date:** **02/20/2025** **Last Revised Date:** **02/20/2025**

OVERVIEW

Carbidopa-levodopa, an aromatic amino acid decarboxylation inhibitor and an aromatic amino acid, is indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.[1-4] Carbidopa-levodopa extended-release tablets, may be split in half but not crushed and Crexont and Rytary must be swallowed whole.

Table 1. Carbidopa-Levodopa Summary Table.[1-4]

Attribute	Dosing	Availability
Carbidopa-levodopa extended-release tablet (generic only)	Start at 50 mg/200 mg BID and increase up to a total of 250 mg/1,000 mg divided into three or more doses.	• 50 mg/200 mg tablets • 25 mg/100 mg tablets
Crexont® (carbidopa-levodopa extended-release capsule)	Start at 35 mg/140 mg BID and increase up to 525 mg/2,100 mg divided up to QID.	• 35 mg/140 mg capsules • 52.5 mg/210 mg capsules • 70 mg/280 mg capsules • 87.5 mg/350 mg capsules
Rytary® (carbidopa-levodopa extended-release capsule)	Start at 23.75 mg/95 mg TID and increase up to 97.5 mg/390 mg TID.	• 23.75 mg/95 mg capsules • 36.25 mg/145 mg capsules • 48.75 mg/195 mg capsules • 61.25 mg/245 mg capsules
Sinemet® (carbidopa-levodopa immediate-release tablets - generic)	Start at 25 mg/100 mg TID and gradually titrate to 8 tablets given throughout the day.	• 10 mg/100 mg tablets • 25 mg/100 mg tablets • 25 mg/250 mg tablets (generic only)

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a Step 1 product prior to the use of a Step 2 product. If the preferred step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the preferred step therapy criteria below.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Preferred Medications:

- generic carbidopa-levodopa tablets, generic carbidopa-levodopa extended-release tablets

Non-preferred Medications:

- Crexont capsules, Rytary capsules

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
Note: A trial of Sinemet also satisfies the requirement.

2. If the patient is currently taking Crexont capsules or Rytary capsules, approve continuation of therapy.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics*; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent*; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the

requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as (*). Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Carbidopa-Levodopa tablets [prescribing information]. Parsippany, NJ: Teva; September 2020.
2. Carbidopa-Levodopa ER tablets [prescribing information]. Bridgwater, NJ: Amneal; December 2022.
3. Crexont® ER capsules [prescribing information]. Bridgwater, NJ: Amneal; August 2024.
4. Rytary® ER capsules [prescribing information]. Bridgwater, NJ: Amneal; December 2019.