

## **Clinical Policy: Carbidopa/Levodopa ER Capsules (Rytary)**

Reference Number: CP.PMN.238

Effective Date: 09.01.20

Last Review Date: 08.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Carbidopa/levodopa extended-release capsules (Rytary<sup>™</sup>) is a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid).

### **FDA Approved Indication(s)**

Rytary is indicated for the treatment of Parkinson's disease (PD), post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Rytary is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Parkinson's Disease or Parkinsonism (must meet all):**

1. Diagnosis of PD or parkinsonism;
2. Age  $\geq$  18 years;
3. Documented intolerance or contraindication\* to carbidopa-levodopa sustained release tablets (Sinemet<sup>®</sup> CR) that would not apply to Rytary;
4. Dose does not exceed carbidopa 612.5 mg/levodopa 2,450 mg per day.

##### **Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

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*\*Examples of acceptable intolerance or contraindications include inability to swallow pills or intolerance or contraindications to excipients in carbidopa-levodopa sustained released tablets. Note: Failure of carbidopa-levodopa sustained released tablets is NOT an acceptable rationale for use of Rytary over Sinemet CR.*

##### **B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Parkinson’s Disease or Parkinsonism (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed carbidopa 612.5 mg/levodopa 2,450 mg per day.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less);** or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

MAO: monoamine oxidase

PD: Parkinson’s disease

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Carbidopa-levodopa sustained released tablets (Sinemet CR)	<p>Patients not currently receiving levodopa: Initial: carbidopa 50 mg/levodopa 200 mg PO BID.</p> <p>Patients currently receiving levodopa: <i>Note: Levodopa must be discontinued at least 12 hours before starting carbidopa/levodopa therapy.</i></p>	Most patients are adequately controlled on doses that provide up to 1,600 mg/day of levodopa.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<p>Initial: Sinemet CR should be substituted at a dosage that will provide approximately 25% of the previous levodopa dosage; usual initial dose in mild to moderate disease is carbidopa 50 mg/levodopa 200 mg BID.</p> <p>Patients converting from immediate-release (IR) formulation to controlled release:                      Initial: Dosage should be substituted at an amount that provides ~10% more of levodopa/day, depending on clinical response, dosage may need to be increased to provide up to 30% more levodopa/day. Total calculated dosage is administered in divided doses at intervals ranging from 4 to 8 hours during waking hours. An interval of at least 3 days between dosage adjustments is recommended.</p>	

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): concomitant use of nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine) or have recently (within 2 weeks) taken a nonselective MAO inhibitor
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
PD; parkinsonism	<p>Levodopa-naïve patients: Starting dose is 23.75 mg/95 mg PO TID; may increase to 36.25 mg/145 mg TID on the fourth day of treatment; may increase dose up to carbidopa 97.5 mg/levodopa 390 mg TID; frequency of dosing may be increased to a maximum of 5 times daily if needed and tolerated.</p> <p>Patients converting from IR carbidopa/levodopa to ER carbidopa-levodopa: The dosages of other carbidopa and levodopa products are not interchangeable on a 1:1 basis with the dosages of Rytary. Initial dose based off of total current daily dose of levodopa in IR carbidopa/levodopa (frequency of dosing may be increased to a maximum of 5 times daily if needed and tolerated).</p>	Carbidopa 612.5 mg /levodopa 2450 mg per day

**VI. Product Availability**

ER capsule: carbidopa/levodopa 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg

**VII. References**

1. Rytary Prescribing Information. Hayward, CA: Impax Laboratories; December 2019. Available at: <https://rytary.com>. Accessed April 27, 2020.
2. Sinemet CR Prescribing Information. Whitehouse Station, NJ: Merck and Co., Inc.; April 2018. Available at <https://dailymed.nlm.nih.gov>. Accessed April 27, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed April 27, 2020.
4. Miyasaki J, Martin W, Suchowesky O. Practice parameter: Initiation of treatment for Parkinson’s disease: (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2002; 58(1):11-17.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy CP.CPA.148; retire CP.CPA.148; added HIM and Medicaid lines of business; no significant changes from previously approved policy; references reviewed and updated.	04.27.20	08.20

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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