

## Pharmacy Medical Necessity Guidelines: Inbrija (levodopa)

Effective: September 1, 2023

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: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan			<b>Fax Numbers:</b> RXUM: 617.673.0988

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

### OVERVIEW

Inbrija (levodopa) is an aromatic amino acid indicated for the intermittent treatment of “off” episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

Inbrija (levodopa) capsules contain levodopa inhalation powder and are for oral inhalation only. Inbrija must be used with Inbrija inhaler.

### COVERAGE GUIDELINES

The plan may authorize coverage of Inbrija (levodopa) when all of the following criteria are met:

1. The member has a diagnosis of Parkinson's disease  
**AND**
2. The member is experiencing intermittent “off” episodes related to Parkinson's Disease  
**AND**
3. Documentation of attempts to adjust dosing or formulation of carbidopa/levodopa to manage “off” symptoms.  
**AND**
4. The member has had an inadequate response or intolerance to one agent from at least TWO of the following classes or contraindication to ALL of the following classes: :
  - a. A dopamine agonist (e.g. pramipexole IR, ropinirole IR)
  - b. A monoamine oxidase-B (MAO-B) inhibitor (e.g. selegiline),
  - c. A catechol-O-methyltransferase (COMT) inhibitor (e.g. entacapone)**AND**
5. Carbidopa/levodopa therapy will be continued concomitantly with Inbrija

### LIMITATIONS

None

### CODES

None

### REFERENCES

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6. Inbrija (levodopa inhalation powder) [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc.; August 2020.

7. Kadastik-Eerme L, Taba N, Asser T et al. Factors associated with motor complications in Parkinson's disease. *Brain Behav.* 2017; 7(10):e00837.
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10. Patel AB, Jimenez-Shahed J. Profile of inhaled levodopa and its potential in the treatment of Parkinson's disease: evidence to date. *Neuropsychiatr Dis Treat.* 2018; 14:2955-64.
11. Sinemet (carbidopa/levodopa) [prescribing information]. Whitehouse Station, NJ: Merck Sharp and Dohme Corp.; March 2020.
12. Talati R, Baker WL, Patel AA et al. Adding a dopamine agonist to preexisting levodopa therapy vs. levodopa therapy alone in advanced Parkinson's disease: a meta analysis. *Int J Clin Pract.* 2009; 63(4):613-23.

### **APPROVAL HISTORY**

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

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: Effective September 1, 2023, updated previous trial language to require trial and failure with at least two therapeutic classes or contraindication to all therapeutic classes.

### **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](#)