Pharmacy Medical Necessity Guidelines:
Inbrija (levodopa)

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

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

1. Bay AA, Hart AR, Michael Caudle W et al. The association between Parkinson's disease symptom side-of-onset and performance on the MDS-UPDRS scale part IV: Motor complications. The association between Parkinson's disease symptom side-of-onset and performance on the MDS-UPDRS scale part IV: Motor complications. *J Neurol Sci*. 2019; 396:262-5.
2. European Parkinson's Disease Association (EPDA). Wearing off and motor fluctuations. 2017. URL: https://epda.eu.com/about-parkinsons/symptoms/motor-symptoms/wearing-off-and-motor-fluctuations/. Available from Internet. Accessed 2019 January 14.
3. Ferreira JJ, Katzenschlager R, Bloem BR et al. Summary of the recommendations of the EFNS/MDS-ES review on therapeutic management of Parkinson's disease. *Eur J Neurol*. 2013; 20(1):5-15.
4. Food and Drug Administration (FDA). Drugs@FDA. URL: http://www.accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2019 January 23.
5. Goetz CG, Tilley BC, Shaftmann SR et al. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): scale presentation and clinimetric testing results. *Mov Disord*. 2008; 23(15):2129-70.

6. Inbrija (levodopa inhalation powder) [prescribing information]. Pearl River, NY: Acorda Therapeutics, Inc.; December 2024.
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.
8. LeWitt PA, Hauser RA, Pahwa R et al. Safety and efficacy of CVT-301 (levodopa inhalation powder) on motor function during off periods in patients with Parkinson's disease: a randomised, double-blind, placebo-controlled phase 3 trial. Lancet *Neurol*. 2019; 18(2):145-154.
9. Pahwa R, Factor SA, Lyons KE et al. Practice Parameter: treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2006; 66(7):983-95.
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.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.
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