Pharmacy Policy Bulletin: J-0862 Inbrija (levodopa) - Commercial and Healthcare Reform	
Number: J-0862	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0862-011	**Original Date:** 01/30/2019
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Inbrija (levodopa) inhalation powder
FDA-Approved Indication(s):	• Intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa

Background:	• Parkinson's disease is characterized by a decrease in dopamine concentrations in the brain leading to movement disorders such as tremor, bradykinesia, and rigidity. Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier, and is converted to dopamine in the brain. • Patients with Parkinson's disease may experience a condition characterized by hypermobility of "off" episodes. "Off" episodes occur when carbidopa/levodopa has worn off and may consist of tremor, slowness, stiffness, difficulty walking or moving, and trouble getting around. For the treatment of motor fluctuations including "off" episodes, the International Parkinson and Movement Disorder Society (IPMDS) recommends adjusting levodopa's timing to shorter intervals, improving absorption by administering levodopa on an empty stomach, and treating constipation to improve gastrointestinal transit. The guidelines also recommend addressing "off" episodes with adjunctive medications. • Prescribing Considerations: ○ In clinical trials, patients had a baseline of at least 2 hours per day of OFF time per day despite carbidopa/levodopa treatment. ○ In clinical trials, patients with asthma, chronic obstructive pulmonary disease (COPD), or other chronic respiratory disease within the last 5 years were excluded. Due to the risk of bronchospasm, Inbrija is not recommended in patients with asthma, COPD, or other chronic underlying lung disease. ○ The maximum dose per off period is 84 mg, and the maximum recommended daily dosage is 420 mg. ○ The safety and effectiveness in pediatric patients have not been established.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Inbrija may be approved when all of the following criteria are met **(A. through D.)**:

- **A.** The member is 18 years of age or older.
- **B.** The member has a diagnosis of Parkinson's disease (ICD-10: G20).
- **C.** The member is experiencing OFF episodes despite an optimally dosed oral carbidopa/levodopa regimen.
- **D.** The member is experiencing at least 2 hours per day of OFF time per day.

II. Reauthorization

When a benefit, reauthorization of Inbrija may be approved when the following criterion is met **(A.)**:

- **A.** The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization will be granted.

Automatic Approval Criteria

None

References:

1. Inbrija [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; August 2020.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018;33(8):1248-1266.
3. Pringsheim T, Day G, Smith D, et al. Dopaminergic Therapy for Motor Symptoms in Early Parkinson Disease Practice Guideline Summary. *Neurology* 2021; 97:942-957.