MEDICAL MUTUAL®

Drug Policy

Policy:	Inbrija (levodopa, inhalation capsule)	Annual Review Date: 11/21/2023 Last Revised Date: 11/21/2023

OVERVIEW

Inbrija is indicated for the intermittent treatment of "off" episodes in patients with Parkinson's disease (PD) treated with carbidopa-levodopa. Inbrija has been shown to be effective only in combination with carbidopa-levodopa. Inbrija should be taken when symptoms of an "off" period start to return. The recommended dosage of Inbrija is 84 mg (two 42 mg capsules) as needed, up to five times daily. The maximum dose per "off" period is 84 mg, and the maximum daily dosage is 420 mg. Inbrija capsules are for oral inhalation only and should be used only with the Inbrija inhaler. Inbrija capsules must not be swallowed. Patients are instructed to load one capsule into the inhaler and breathe in; then remove the used capsule and load the second capsule into the inhaler and breathe in. The Inbrija inhaler is breath-actuated by the patient.

POLICY STATEMENT

This policy involves the use of Inbrija. Prior authorization is recommended for pharmacy benefit coverage of Inbrija. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Inbrija as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Inbrija be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inbrija is recommended in those who meet the following criteria:

1. <u>Parkinson's Disease, Patients with "Off" Episodes</u>

Criteria. *Patient must meet the following criteria (A, B, C, <u>and</u> D):*

A. Inbrija is prescribed by or in consultation with a neurologist; AND
B. The patient is currently taking carbidopa-levodopa; AND
C. The patient has previously tried one of; entacapone, rasagiline, pramipexole, ropinirole, tolcapone, Apokyn, cabergoline, selegiline, or Xadago for the treatment of "off" episodes; AND

D. Patient does not have asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Inbrija has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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. Inbrija™ powder for inhalation [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc.; October 2020.
2. Connolly BS, Lang AE. Pharmacological treatment of Parkinson disease. A review. *JAMA*. 2014;311(16):1670-1683.
3. National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's disease information page. Last updated: Aug, 2019. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Parkinsons-Disease-Information-Page. Accessed on November 4, 2020.
4. 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;66:983-995.
5. levodopa. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated on 06 November 2019. Accessed on 13 November 2019.