Pharmacy Policy Bulletin

Title: Levodopa Inhalation (Inbrija™)
Policy #: Rx.01.219

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:
The intent of this policy is to communicate the medical necessity criteria for levodopa inhalation (Inbrija™) as provided under the member’s prescription drug benefit.

Description:
Parkinson’s disease (PD) is a neurodegenerative disorder caused by progressive dopamine depletion in the nigrostriatal pathway of the brain. PD is characterized by manifestations of tremor, bradykinesia, and rigidity. PD is a motor condition that includes neuropsychiatric and other nonmotor manifestations.

The dopamine precursor levodopa is the most effective drug for the symptomatic treatment of PD, however; levodopa-induced complications (eg, motor fluctuations [“wearing off” phenomenon], dyskinesia, dystonia) develop in at least 50% of patients after 5 to 10 years of levodopa treatment. The risk of motor complications increases with higher levodopa doses and younger age of PD onset.

The cause of motor fluctuations is not clear, but it is hypothesized that they evolve as PD progresses because progressive degeneration of the nigrostriatal dopaminergic pathway reduces the ability of nerve terminals to store and release dopamine. The response to exogenous levodopa becomes more pulse-like due to the inability of the nerve terminals to store and release dopamine. Levodopa has a short half-life (90 minutes), rapid cycling pharmacokinetics (PK), and erratic intestinal absorption related to slowed intestinal motility.

Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and is presumably converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of PD.

Levodopa (Inbrija) inhalation powder is indicated for the intermittent treatment of OFF episodes in patients with PD treated with carbidopa/levodopa.

Policy:
Levodopa inhalation (Inbrija) will be approved when ALL of the following criteria are met:

1. Diagnosis of Parkinson’s disease and member is experiencing intermittent off episodes; and
2. Concurrent use of carbidopa/levodopa containing product; and
3. Prescribed by or in consultation with a neurologist; and
4. Member had inadequate response or inability to tolerate ONE of the following:

   a. MAO-B Inhibitor (e.g., rasagiline, selegiline)
   b. Dopamine Agonist (e.g., pramipexole, ropinirole)
   c. COMT inhibitor (e.g., entacapone)

**Black Box Warning as shown in the drug Prescribing Information:**
None

**Guidelines:**
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Inbrija™</td>
<td>Levodopa inhalation</td>
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**Cross References:**
Rx.01.33 Off-Label Use

<table>
<thead>
<tr>
<th>Policy Version Number:</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>July 11, 2019</td>
</tr>
<tr>
<td>Policy Effective Date:</td>
<td>October 01, 2019</td>
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<td>Next Required Review Date:</td>
<td>July 11, 2020</td>
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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.