Inbrija

**Description**

Inbrija (levodopa inhalation powder)

**Background**

Inbrija consists of a dry powder formulation of levodopa for oral inhalation with the Inbrija inhaler. Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson’s disease (1).

**Regulatory Status**

FDA-approved indications: Inbrija is an aromatic amino acid indicated for the intermittent treatment of OFF episodes in patients with Parkinson’s disease treated with carbidopa/levodopa (1).

Inbrija is contraindicated in patients currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine) or who have recently (within 2 weeks) taken a nonselective MAO inhibitor. Hypertension can occur if these drugs are used concurrently (1).

Patients treated with levodopa have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles. Before treatment with Inbrija is initiated, patients should be advised about the potential to develop drowsiness and that there is an increased risk for somnolence with the concomitant use of sedating medications and the presence of sleep disorders (1).
Patients with a major psychotic disorder should ordinarily not be treated with Inbrija due to the risk of exacerbating psychosis and causing hallucinations. In addition, medications that antagonize the effects of dopamine used to treat psychosis may exacerbate the symptoms of Parkinson’s disease and may decrease the effectiveness of Inbrija (1).

The maximum dose per OFF period is 84 mg, and the maximum recommended daily dosage of Inbrija is 420 mg (1).

The safety and effectiveness of Inbrija in pediatric patients under 18 years of age have not been established (1).

**Related policies**
Nourianz, Nuplazid

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**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Inbrija may be considered **medically necessary** in patients 18 years of age or older with Parkinson’s disease and if the conditions indicated below are met.

Inbrija is considered **investigational** for patients less than 18 years of age and for all other indications.

### Prior-Approval Requirements

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

- Parkinson’s disease experiencing OFF episodes

**AND ALL** of the following:

1. Used in combination with carbidopa/levodopa
2. Inadequate control of Parkinson’s symptoms on maximum tolerated doses of oral carbidopa/levodopa therapy
3. **NO** asthma or chronic obstructive pulmonary disease (COPD)
4. **NO** concomitant use of a nonselective monoamine oxidase inhibitor (MAOI), such as phenelzine or tranylcypromine (must be >14 days post discontinuing therapy)

**Prior – Approval Renewal Requirements**

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

- Parkinson’s disease experiencing OFF episodes

AND ALL of the following:

1. Improvement in Parkinson’s symptoms
2. Used in combination with carbidopa/levodopa
3. **NO** asthma or chronic obstructive pulmonary disease (COPD)
4. **NO** concomitant use of a nonselective monoamine oxidase inhibitor (MAOI), such as phenelzine or tranylcypromine

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity**

<table>
<thead>
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<th>Medication</th>
<th>Quantity Limit per 90 days</th>
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<td>42 mg capsules</td>
<td>900 capsules per 90 days</td>
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**Duration**

6 months
Prior – Approval *Renewal* Limits

**Quantity**

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**Duration**

12 months

**Rationale**

**Summary**

Inbrija consists of a dry powder formulation of levodopa for oral inhalation with the Inbrija inhaler. Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson’s disease. The safety and effectiveness of Inbrija in pediatric patients under 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Inbrija while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

<table>
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<tr>
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<th>Action</th>
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<tbody>
<tr>
<td>March 2019</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review. Addition of requirement of no asthma or COPD per SME</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.