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5.60.031

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	March 22, 2019
Subject:	Inbrija	**Page:**	1 of 4

Last Review Date: June 13, 2024

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 indication: 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, Tasmar

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** if the conditions indicated below are met.

Inbrija may be considered **investigational** 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

Medication	Quantity Limit
42 mg capsules	900 capsules per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

Medication	Quantity Limit

42 mg capsules	900 capsules per 90 days

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

1. Inbrija [package Insert]. Ardsley, NY: Acorda Therapeutics, Inc.; December 2022.

Policy History

Date	Action
March 2019	Addition to PA
June 2019	Annual review. Addition of requirement of no asthma or COPD per SME
December 2019	Annual review
December 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual review
June 2023	Annual review and reference update. Changed policy number to 5.60.031
December 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.