UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2164-8
Program	Prior Authorization/Medical Necessity
Medication	Inbrija® (levodopa inhalation powder)
P&T Approval Date	5/2019, 7/2019, 7/2020, 12/2020, 2/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

1. Background:

Inbrija® (levodopa inhalation powder) is an aromatic amino acid indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

Inbrija should only be administered with the Inbrija inhaler.

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Inbrija** will be approved based on **all** of the following criteria:

   a. Diagnosis of Parkinson's disease

   -AND-

   b. **Inbrija** will be used as intermittent treatment for OFF episodes[1]

   -AND-

   c. Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

   -AND-

   d. Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

   -AND-

   e. Patient continues to experience ≥ 2 hours of OFF time per day despite optimal management of carbidopa-levodopa therapy including **both** of the following:

      (1) Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet

-AND-

(2) Dose and dosing interval optimization

-AND-

f. History of failure, contraindication, or intolerance to **two** anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

(1) Dopamine agonists (e.g., pramipexole, ropinirole)
(2) Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
(3) Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Inbrija** will be approved based on the following criterion:

a. Documentation of positive clinical response to **Inbrija** therapy

-AND-

b. Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Step Therapy may be in place.

4. References:

1. Inbrija [package insert]. Pearl River, NY: Acorda Therapeutics, Inc.; December 2022.
2. LeWitt P, Hauser R, Pahwa R et al. Safety and efficacy of CVT-301 (levodopa inhalation powder) on motor function during off periods in patients with Parkinson's disease: a randomised, double-blind, placebo-controlled phase 3 trial. The Lancet Neurology. 2019;18(2):145-154.

3. Tarsy D. UpToDate. Medical management of motor Fluctuations and Dyskinesia in Parkinson Disease. 2024 Sep. 23. Accessed December 20, 2024.

Program	Prior Authorization/Medical Necessity - Inbrija® (levodopa inhalation powder)
Change Control	
5/2019	New program
7/2019	Updated clinical coverage criteria regarding prior anti-Parkinson's therapies.
7/2020	Annual review. No changes to coverage criteria.
12/2020	Removed evaluation of underlying lung disease from review criteria. Updated references.
2/2022	Annual review with no change in clinical criteria.
2/2023	Annual review with no change in clinical criteria. Updated references.
2/2024	Annual review. Revised initial authorization to 12 months. Updated references.
2/2025	Annual review with no change in clinical criteria. Updated references.