UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Inbrija

Program	Prior Authorization
Medication	Inbrija® (levodopa inhalation powder)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, New York, New York EPP, Nevada, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2019
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

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.[1]

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. Inbrija will be approved based on **<u>all</u>** of the following criteria:

a. Diagnosis of Parkinson's disease

-AND-

b. Inbrija will be used as intermittent treatment for OFF episodes

-AND-

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

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-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
(2) Dose and dosing interval optimization

-AND-

f. History of failure, contraindication, or intolerance to **two** anti-Parkinson's disease therapies 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., selegiline)

Authorization will be issued for 6 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.

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 may be in place.

4. References:

1. Inbrija [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; August 2020.
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. Motor Fluctuations and Dyskinesia in Parkinson Disease. 2019 Feb. 20. Accessed April 2, 2019.

Program	Prior Authorization
Change Control	
Date	Change
5/2019	New program
7/2019	Changed step therapy medication requirement from a trial of three to a trial of two.
7/2020	Annual review. No changes to coverage criteria. Added Clinical Rules Section. Updated reference.
12/2020	Removed evaluation of underlying lung disease from review criteria. Updated references.