

SPECIALTY GUIDELINE MANAGEMENT

INBRIJA (levodopa inhalation powder)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Inbrija is indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Parkinson's disease

Authorization of 6 months may be granted for intermittent treatment of "off" episodes in members with Parkinson's disease when all of the following criteria are met:

- A. The member experiences at least 2 hours per day of "off" time
- B. The member is currently being treated with oral carbidopa/levodopa
- C. Attempts to manage "off" episodes by adjusting the dosing or formulation of carbidopa/levodopa were ineffective
- D. Treatment with carbidopa/levodopa plus one of the following therapies was ineffective at managing "off" episodes:
 1. Dopamine agonist (e.g., pramipexole, ropinirole)
 2. Monoamine oxidase B (MAO-B) inhibitor (e.g., selegiline, rasagiline)
 3. Catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone, tolcapone)

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for intermittent treatment of "off" episodes in members with Parkinson's disease when all of the following criteria are met:

- A. The member is currently being treated with oral carbidopa/levodopa
- B. The member is experiencing improvement on Inbrija therapy (e.g., reduction in daily off time, improvement in motor function post-administration)

IV. REFERENCES

1. Inbrija [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; June 2022.
2. Miyasaki JM, Martin W, Suchowersky O, et al. Practice parameter: Initiation of treatment for Parkinson's disease: An evidence-based review. *Neurology* Jan 2002, 58 (1) 11-17.

| Reference number(s) |
|---------------------|
| 2860-A |

3. National Institute for Clinical Excellence: Parkinson's disease in adults. July 2017.
<https://www.nice.org.uk/guidance/ng71/resources/parkinsons-disease-in-adults-pdf-1837629189061>.
Accessed August 16, 2022.
4. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018; 33(8):1248-1266.