

Specialty Guideline Management Inbrija

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Inbrija	levodopa

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 Indication¹

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.

Coverage Criteria

Parkinson's disease¹⁻⁴

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:

• The member experiences at least 2 hours per day of "off" time.

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- The member is currently being treated with oral carbidopa/levodopa.
- Attempts to manage "off" episodes by adjusting the dosing or formulation of carbidopa/levodopa were ineffective.
- Treatment with carbidopa/levodopa plus one of the following therapies was ineffective at managing "off" episodes:
 - Dopamine agonist (e.g., pramipexole, ropinirole)
 - Monoamine oxidase B (MAO-B) inhibitor (e.g., selegiline, rasagiline)
 - Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone)

Continuation of Therapy

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

- The member is currently being treated with oral carbidopa/levodopa.
- The member is experiencing improvement with the requested medication (e.g., reduction in daily "off" time, improvement in motor function post-administration).

References

- 1. Inbrija [package insert]. Pearl River, NY: Acorda Therapeutics, Inc.; December 2022.
- National Institute for Health and Care Excellence (NICE) guideline: Parkinson's disease in adults. Published July 19, 2017. Accessed August 12, 2024. https://www.nice.org.uk/guidance/ng71/resources/parkinsons-disease-in-adults-pdf-1837629189061.
- 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 [published correction appears in Mov Disord. 2018 Dec;33(12):1992]. Mov Disord. 2018;33(8):1248-1266. doi:10.1002/mds.27372
- LeWitt PA, Hauser RA, 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 [published correction appears in Lancet Neurol. 2019 Mar;18(3):e2]. Lancet Neurol. 2019;18(2):145-154. doi:10.1016/S1474-4422(18)30405-8

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