CVS Caremark®

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

# 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.
* 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.
2. 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.
3. 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
4. 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