PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Inbrija Prior Authorization Policy
- Inbrija™ (levodopa inhalation powder for oral inhalation use – Acorda)

REVIEW DATE: 08/19/2020

OVERVIEW

Inbrija, an aromatic amino acid, is indicated for the intermittent treatment of "off" episodes in patients with Parkinson's disease treated with carbidopa-levodopa.[1] Inbrija should be taken when symptoms of an "off" period start to return. The recommended dosage of Inbrija is 84 mg (two 42 mg capsules) as needed, up to five times daily. Inbrija capsules are for oral inhalation only and should be used only with the Inbrija inhaler. Inbrija capsules must not be swallowed. Patients are instructed to load one capsule into the inhaler and breathe in; then remove the used capsule and load the second capsule into the inhaler and breathe in. The Inbrija inhaler is breath-actuated by the patient.

Guidelines

The American Academy of Neurology published guidelines in 2006 on the treatment of Parkinson's disease with motor fluctuations and dyskinesia.[2] The guidelines are dated and do not include more recently approved medications. It is recommended to offer entacapone and rasagiline to reduce "off" time (Level A). Pergolide (withdrawn from the market in 2007 due to risk of valvular fibrosis), pramipexole, ropinirole, and tolcapone (used with caution; requires monitoring for hepatotoxicity) should be considered to reduce "off" time (Level B). Apokyn® (apomorphine hydrochloride injection), cabergoline, and selegiline may be used to reduce "off" time (Level C). According to the guidelines, the available evidence does not establish superiority of one medication over another in reducing "off" time (Level B). Sustained-release levodopa/carbidopa and bromocriptine should not be considered to reduce "off" time (Level C). Amantadine may be used to reduce dyskinesia (Level C).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Inbrija. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Inbrija as well as the monitoring required for adverse events and long-term efficacy, approval requires Inbrija to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inbrija is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Parkinson's Disease.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is currently taking carbidopa-levodopa; AND
   - **B)** Patient is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **C)** Patient has previously tried one other treatment for "off" episodes and meets ONE of the following criteria (i or ii):
     - **i.** Patient had significant intolerance, according to the prescriber; OR
     - **ii.** Patient had inadequate efficacy, according to the prescriber; AND

     Note: Examples of treatments for "off" episodes are entacapone, rasagiline, pramipexole, ropinirole, tolcapone, Apokyn, cabergoline, selegiline, Ongentys, Kynmobi, or Xadago.
   - **D)** Patient does not have asthma, chronic obstructive pulmonary disease, or other chronic underlying lung disease; AND
   - **E)** Inbrija is prescribed by or in consultation with a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Inbrija is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Inbrija™ powder for inhalation [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc.; September 2019.
2. Pahwa R, Factor SA, Lyons KE, et al. Practice parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the quality standards subcommittee of the American Academy of Neurology. Neurology. 2006;66:983-995.