levodopa (Inbrija ™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO044

Description

Levodopa (Inbrija) is an orally inhaled metabolic precursor to dopamine used to relieve symptoms of Parkinson's disease.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
levodopa (Inbrija)	42 mg capsules	Parkinson's Disease	120 capsules/30 days*

*Maximally allowed does upon clinical review for medical necessity: 300 capsules/30 days

Initial Evaluation

I. Levodopa (Inbrija) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by, or in consultation with, a neurologist; **AND**
   B. Not used in combination with apomorphine (Apokyn, Kynmobi); **AND**
   C. Documentation that member does **not** have a diagnosis of chronic respiratory disease (e.g. COPD, asthma, etc.); **AND**
   D. A diagnosis of **Parkinson's Disease (PD)** when the following are met:
      1. Documentation that the member has moderate to severe Parkinson's disease symptoms; **AND**
      2. Is currently on an oral levodopa regimen at least 3 times a day for a minimum of 2 weeks prior to starting levodopa (Inbrija); **AND**
      3. Documentation that the member has a decrease in wearing off symptoms in response to the member's usual morning dose of levodopa; **AND**
      4. Prescriber attest that member will be using levodopa (Inbrija) in combination with carbidopa/levodopa; **AND**
      5. The quantity requested is 120 capsules per 30 days; **OR**
         i. Documentation of medical necessity for dose escalation; **AND**
         ii. Attestation that the member has been taught how to prepare and use the inhaler system appropriately; **AND**
         iii. Attestation that the member is able to administer the full dose of levodopa (Inbrija); **AND**

6. Treatment with the following has been ineffective, contraindicated or not tolerated:
    i. Carbidopa/levodopa IR up to five times a day OR carbidopa/levodopa XR; **AND**
    ii. ONE of the following:
        a. Dopamine agonist (e.g. pramipexole, ropinirole, rotigotine)
        b. monoamine oxide –B (MAO-B) inhibitor (e.g. selegiline, rasagiline, safinamide)
        c. Catechol-O-methyl transferase (COMT) inhibitors (e.g. entacapone, tolcapone).

II. Levodopa (Inbrija) is considered <u>investigational</u> when used for all other conditions, including but <u>not</u> limited to:
    A. Mild Parkinson's disease symptoms
    B. Parkinson's disease WITHOUT documentation of motor fluctuations, "wearing off" phenomenon

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Prescriber attests that member will be using levodopa (Inbrija) in combination with carbidopa/levodopa ; **AND**
IV. Documentation that member has a reduction in wearing off period from baseline

Supporting Evidence

I. Moderate to severe Parkinson's disease symptoms were defined in the pivotal SPAM^{SM}-PD trial as a modified Hoehn and Yahr (H&Y) rating 22 of stages 1-3 in the ON state and recognizable, predictable OFF episodes totaling ≥2 hours per day (excluding early-morning OFF time).
II. A UPDRS Part III score of ≥ 25% after the patient's usual morning dose of levodopa reflects that the patient's wearing off motor symptoms are responsive to levodopa treatment.
III. Patients who were taking apomorphine (Apokyn) were excluded from the SPAM^{SM}-PD trial
IV. Due to the safety concerns, patients with chronic respiratory disease are excluded from the SPAM^{SM}-PD trial.

V. Levodopa (Inbrija) has only been shown to be effective in combination with carbidopa/levodopa.

VI. According to the American Family Physician diagnosis and treatment guideline for Parkinson's disease, the treatment algorithm for motor complication is:

- Fractionate carbidopa/levodopa therapy five times a day and consider adding a dopamine agonist, MAO-B inhibitor, OR COMT inhibitor.

VII. Levodopa (Inbrija) has not been studied in patients with mild Parkinson's disease or Parkinson 's disease without motor fluctuations; therefore, it would be considered investigational when Inbrija is requested in those settings.

References

1. Inbrija [Prescribing Information]. Acorda Therapeutics: Ardsley, NY. December 2018.
2. LeWitt P, 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. Lancet Neurol. 2019 Feb;18(2):145-154. doi: 10.1016/S1474-4422(18)30405-8.
3. UpToDate, Inc. Motor fluctuations and dyskinesia in Parkinson disease. UpToDate [Online Database]. Waltham, MA. Last updated July 12, 2018. Available from: http://uptodate.com/home/index.html. Accessed February 11, 2019.
4. Rao S., M.D., Hofmann L., M.D., and Shakil A., M.D. Parkinson's Disease: Diagnosis and Treatment. University of Texas Southwestern Medical School at Dallas Family Medicine Residency Program, Dallas, Texas. Am Fam Physician. 2006 Dec 15;74(12):2046-2054.

Policy Implementation/Update:

Action and Summary of Changes	Date
Updated formatting of QL table, improved clarity of policy requirement around previous agents trialed, added renewal requirement of continuing carbidopa/levodopa, and removed renewal requirement of 'absence of unacceptable toxicities.' Addition of new standard renewal language noting previous approvals and member is not continuing via samples.	04/2021
Policy Created	05/2019