PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Lodosyn® (carbidopa tablets, generics)

APPROVAL DATE: 08/28/2019

OVERVIEW

Lodosyn is indicated for use with carbidopa-levodopa or with levodopa in the treatment of the symptoms of idiopathic Parkinson's disease (paralysis agitans), postencephalitic parkinsonism, and symptomatic parkinsonism, which may follow injury to the nervous system by carbon monoxide intoxication and/or manganese intoxication.[1] Carbidopa inhibits decarboxylation of peripheral levodopa, reduces the amount of levodopa required to produce a given response by about 75% and, when administered with levodopa, increases both plasma levels and the plasma half-life of levodopa.

Disease Overview

PD is a common neurodegenerative disease and is a chronic, progressive disorder of the extrapyramidal nervous system affecting the mobility and control of the skeletal muscular system.[2,3] Its characteristic features include resting tremor, rigidity, bradykinetic movements, and postural instability.[2,3] As these symptoms become more pronounced, patients with PD may have difficulty walking, talking, or completing other simple tasks. Early symptoms of PD are subtle and occur gradually. The disease course varies considerably as well as the intensity of symptoms. Resting tremor is the major symptom for some individuals, while for others tremor is only a minor complaint and other manifestations may be more troublesome. It is not possible to predict which symptoms will affect an individual. PD symptoms are thought to be related to depletion of dopamine in the corpus striatum. Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and is believed to be converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa relieves PD symptoms. Other medications are also utilized to improve mobility.

Guidelines

According to the American Academy of Neurology guideline (2002) on the initiation of treatment for PD, levodopa, cabergoline, ropinirole, and pramipexole are effective in ameliorating motor and activities of daily living disability in patients with PD who require dopaminergic therapy.[4] The guideline states that levodopa is more effective than cabergoline, ropinirole, and pramipexole in treating these features of PD. In patients with PD who require dopaminergic treatment, levodopa or a dopamine agonist may be used. The choice should be individualized based on the relative impact of improving motor disability (which is better with levodopa) as compared with the lessening of motor complications (which is better with dopamine agonists).

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lodosyn 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 and B):
   A) Patient is currently receiving carbidopa/levodopa therapy; AND
   B) Lodosyn is being prescribed by, or in consultation with, a neurologist.

2. **Postencephalitic Parkinsonism.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is currently receiving carbidopa/levodopa therapy; AND
   B) Lodosyn is being prescribed by, or in consultation with, a neurologist.

3. **Symptomatic Parkinsonism.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is currently receiving carbidopa/levodopa therapy; AND
   B) Lodosyn is being prescribed by, or in consultation with, a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lodosyn has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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. Lodosyn® [prescribing information] Bridgewater, NJ: Aton Pharma; February 2017.
2. Connolly BS, Lang AE. Pharmacological treatment of Parkinson disease. A review. *JAMA*. 2014;311(16):1670-1683.
3. National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's disease information page. Page last updated: March 27, 2019. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Parkinsons-Disease-Information-Page. Accessed on June 12, 2019.
4. Miyasaki JM, Martin W, Suchowersky O, et al. Practice parameter: initiation of treatment for Parkinson's disease: an evidence-based review. Report of the quality standards subcommittee of the American Academy of Neurology. *Neurology*. 2002;58:11-17.