Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Duopa (carbidopa/levodopa)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2016***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process Duopa (carbidopa/levodopa).

Duopa (carbidopa/levodopa) is indicated for Treatment of motor fluctuations in patients with advanced Parkinson's disease.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Duopa (carbidopa/levodopa), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a neurologist
- Must have adequate trial of a concomitant therapy with carbidopa/levodopa, a dopamine agonist (i.e. pramipexole), and a monoamine oxidase-B (MAO-B)(i.e. rasagiline) inhibitor or catechol O-methyltransferase (COMT) (i.e. entacapone) inhibitor with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies.
- Must have a diagnosis of advanced Parkinson's Disease, with a clear motor response to levodopa, including the following:
    - Chart documentation of motor fluctuations including initial benefit after dose of levodopa followed by return of parkinsonian features before onset of benefit from subsequent dose (wearing off)
    - Chart documentation of trial and failure of increased dose of levodopa with failure defined as either lower doses of levodopa dosed more frequently resulting in no evident clinical response or higher doses of levodopa at the same dosing interval resulting in "on" state dyskinesia (peak dose dyskinesia)
    - Chart documentation of the Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) Part III motor subscale
- Must have documentation that the patient or caregiver is able to care for the gastrostomy tube and the pump to infuse the medication

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Duopa[package insert]. North Chicago, IL: AbbVie Inc.; May 2015.
2. Olanow CW, Kieburtz K, Odin P. Continuous intrajejunal infusion of levodopa/carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomized, controlled, doubleblind, double-dummy study. *Lancet Neurol*. 2014; 13:141-49.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*