Medical Drug Clinical Criteria

Subject:	Duopa (carbidopa and levodopa enteral suspension)		
Document #:	CC-0035	**Publish Date**:	09/19/2022
Status:	Revised	**Last Review Date**:	08/19/2022

Table of Contents

Overview

This document addresses the use of Duopa (carbidopa and levodopa enteral suspension) infusion for the treatment of late-stage Parkinson's disease (PD) in individuals who have poor function (as defined by more "off" periods and fluctuations between "on/off" periods and/or dyskinesias) despite optimal medical therapy.

PD is a progressive neurodegenerative disorder associated with motor complications such as tremor, bradykinesia, and rigidity. The decision to initiate pharmacologic therapy for the management of symptoms associated with PD is determined by the degree to which the individual is functionally impaired and influenced by a variety of individual and medication-related factors. Treatment is individualized and combination therapy is often employed to manage symptoms and reduce "off" episodes (refers to "end-of-dose wearing off" and unpredictable "on/off" episodes).

Levodopa and dopamine agonists are approved as first-line treatment options for early PD. Dopamine agonists, MAO B inhibitors, or COMT inhibitors can be used as adjunct therapy to levodopa in individuals who have continued motor symptoms despite optimal levodopa therapy. At least one agent from each drug class is available as a generic product.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Duopa (carbidopa and levodopa enteral suspension)

Initial requests for Duopa (carbidopa and levodopa enteral suspension) may be approved if the following criteria are met:

I. Individual has a diagnosis of advanced Parkinson's disease with complicated motor fluctuations; **AND**
II. Individual is using via a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) or naso-jejunal tube;
III. Documentation is provided that symptoms have not been adequately controlled with optimal medical therapy which includes the following:
   A. Oral levodopa-carbidopa; **AND**
   B. Dopamine agonists; **AND**
   C. One agent from the following classes:
      1. Catechol-0-methyl transferase (COMT) inhibitor; **OR**
      2. Monoamine oxidase B (MAO B) inhibitor; OR
      3. Adenosine receptor antagonist (Nourianz).

Continuation requests for Duopa (carbidopa and levodopa enteral suspension) may be approved if the following criteria are met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Duopa (carbidopa and levodopa enteral suspension) may not be approved for the following:

I. Individual is receiving a nonselective MAO inhibitor (such as phenelzine or tranylcypromine); **OR**
II. Individual has a diagnosis of atypical PD or secondary PD; **OR**
III. When requesting for all other conditions, or when the above criteria are not met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension, 100 ml

ICD-10 Diagnosis

G20	Parkinson's disease

Document History

Revised: 08/19/2022
Document History:

- 08/19/2022 – Annual Review: Added continuation requirements. Added adenosine receptor antagonist (Nourianz) to initial therapy section per meeting amendment. Coding reviewed: No changes.
- 08/20/2021- Annual Review: No changes. Coding reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 08/21/2020 – Annual Review: Update criteria to clarify route of administration for Duopa. Coding reviewed: No changes.
- 11/15/2019 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes
- 08/17/2018 – Annual Review: Initial review of DRUG.00064. Minor wording and formatting changes for clarity.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 12, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.