Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Carbidopa and levodopa enteral suspension (Duopa)	MP-RX-FP-22-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Carbidopa and levodopa enteral suspension (Duopa) , a drug approved by the Food and Drug Administration (FDA) 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.

Background Information

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.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
G20	Parkinson's disease

Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Duopa (carbidopa and levodopa enteral suspension)

A. Criteria for Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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).

B. Criteria for Continuation of Therapy

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MMM considers continuation of Duopa (carbidopa and levodopa enteral suspension) therapy in patients requesting if for a diagnosis listed above when the following criteria are met:

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

C. Authorization Duration

I. Initial and Reauthorization Duration: 1 year

D. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Drug	Recommended Dosing Schedule
Carbidopa and levodopa enteral suspension (Duopa)	• The maximum recommended daily dose of DUOPA is 2000 mg of levodopa (i.e., one cassette per day) administered over 16 hours

Exceptions
None

Reference Information

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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Annual Review 08/15/2024	Added the following statement to the initial approval criteria section: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.); Added authorization duration; Added dosing information in the Quantity Limits section; wording and formatting changes; Coding reviewed: No change	2/18/2025	3/6/2025
Policy Inception 08/18/2024	Elevance Health's Medical Policy adoption.	N/A	11/30/2023