Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Carbidopa and levodopa enteral suspension (Duopa)	**MP-RX-FP-22-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **7/1/2026**	**7/1/2026** **Frequently Revision:** **Annual**

Service Category:

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other: 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.

Approved Indications

A. For the treatment of motor fluctuations in patients with advanced Parkinson's disease.

Other Uses

A. None.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Carbidopa and levodopa enteral suspension (Duopa)	MP-RX-FP-22-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/1/2026
			Last Review Date: 7/1/2026	Frequently Revision: Annual

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.

Carbidopa and levodopa enteral suspension (Duopa®) (These coverage criteria have been developed in accordance with LCD L33794, External Infusion Pumps, and its associated Policy Article, as applicable to levodopa-carbidopa enteral suspension administered via an external infusion pum)

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.)*

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 motor fluctuations; **AND**
ii. Individual has levodopa-responsive idiopathic Parkinson's disease; **AND**
iii. Duopa will be administered via a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) for long-term administration or via naso-jejunal tube for short-term temporary administration prior to PEG-J placement; **AND**
iv. One of the following is met:
   A. The dosage and/or dosing interval of non-infusion-based Parkinson's disease therapy cannot be further optimized due to intolerance, dyskinesia, and/or other side effects/adverse events, and the individual continues to experience all of the following:
      1. Inadequate control of motor fluctuation symptoms affecting daily living, such as unpredictable increase in stiffness, tremor, or bradykinesia; **AND**
      2. A minimum of 2.5 hours of "off" time per day; **OR**
   B. Individual is currently being treated with an infusion-based Parkinson's disease therapy and is being transitioned to a different infusion-based Parkinson's disease therapy.

B. Criteria For Continuation of Therapy

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. Documentation is provided that there is clinically significant improvement or stabilization in clinical signs and symptoms of disease defined as an increase of on-time with a decrease in the number of off episodes compared to baseline.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Carbidopa and levodopa enteral suspension (Duopa)	MP-RX-FP-22-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/1/2026
			Last Review Date: 7/1/2026	Frequently Revision: Annual

ii. Reauthorization Approval Duration: Up to 12 months

D. Conditions Not Covered

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

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

i. Individual is receiving a nonselective MAO inhibitor (including but not limited to phenelzine or tranylcypromine); **OR**
ii. Individual has a diagnosis of atypical PD or secondary PD; **OR**
iii. When the above criteria are not met and for all other indications.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Carbidopa and levodopa enteral suspension (Duopa)	MP-RX-FP-22-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/1/2026
			Last Review Date: 7/1/2026	Frequently Revision: Annual

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.

Drug	Recommended Dosing Schedule
Carbidopa and levodopa enteral suspension (Duopa) 4.63 mg carbidopa and 20 mg levodopa per mL	• The maximum recommended daily dose of DUOPA is 2000 mg of levodopa (i.e., one cassette per day) administered over 16 hours
Exceptions	
• Evaluate vitamin B6 levels prior to starting treatment with carbidopa/levodopa therapies. • Prior to initiating DUOPA, convert patients from all forms of levodopa to oral immediate-release carbidopa-levodopa tablets (1:4 ratio) • Titrate total daily dose based on clinical response for the patient.	

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Carbidopa and levodopa enteral suspension (Duopa)	**MP-RX-FP-22-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023**	**7/1/2026**
			Last Review Date: **7/1/2026**	**Frequently Revision:** **Annual**

Codes Information:

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.

ICD-10 Diagnostic Codes:

Codes	Description
G20.A1-G20.C	Parkinson's disease

HCPCS Codes:

Codes	Description
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension, 100 ml [Duopa]

Reference Information:

1. AbbVie Inc. (2026). *Duopa® (carbidopa and levodopa) enteral suspension prescribing information*. Revised March 2026. Accessed April 29, 2026. https://www.rxabbvie.com/pdf/duopa_pi.pdf
2. Centers for Medicare & Medicaid Services. (2026). *Local Coverage Determination (LCD): External Infusion Pumps (L33794).* Medicare Coverage Database. Revision effective date January 25, 2026. Accessed April 29, 2026.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
5. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 12, 2022.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically
8. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study [published correction appears in Lancet Neurol. 2014 Mar;13(3):240]. Lancet Neurol. 2014;13(2):141-149. doi:10.1016/S1474-4422(13)70293-X

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.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Carbidopa and levodopa enteral suspension (Duopa)	**MP-RX-FP-22-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **7/1/2026**	**7/1/2026** **Frequently Revision:** **Annual**

Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated the initial approval criteria for Duopa to align with FDA-approved indication language and applicable CMS guidance under LCD L33794, External Infusion Pumps, including criteria for infusion-based therapy for Parkinson's disease. Updated clinical criteria for continuation therapy verbiage to align with other Parkinson's agents. Added available dosage form and exceptions to the recommended dosage table. Coding Reviewed: Updated description for HCPCS J7340. Removed ICD-10-CM G20 and added G20.A1-G20.C. Wording and formatting changes. Updated references and incorporated new policy template.	6/19/2026	7/1/2026
Annual Review	Wording and formatting changes; coding reviewed: No change	8/25/2025	9/8/2025
Annual Review	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	8/14/2024: Elevance Health's Medical Policy adoption.	N/A	11/30/2023