Reference number(s)
7326-A

Standard Medicare Part B Management Duopa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Duopa	carbidopa and levodopa

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[2]

Duopa is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease (PD).

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Parkinson's Disease[1,2]

Authorization of 12 months may be granted for treatment of Parkinson's disease when the member is diagnosed with levodopa-responsive idiopathic Parkinson's disease and either of the following criteria are met:

- 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 member continues to experience both of the following:
  - Inadequate control of motor fluctuation symptoms affecting daily living (e.g., unpredictable increase in stiffness, tremor, bradykinesia).
  - The member has a minimum of 2.5 hours of "off" time per day.
- The member 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.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Duopa.
- Duopa is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Duopa.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- External Infusion Pumps Local Coverage Determination (L33794)

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After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Duopa are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information and the External Infusion Pumps Local Coverage Determination (L33794).

References

1. External Infusion Pumps LCD (L33794) Version R33. Available at: https://www.cms.gov/medicare-coverage-database/search.aspx. Accessed December 15, 2025.
2. Duopa [package insert]. North Chicago, IL: AbbVie Inc.; May 2025.

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