

<b>Policy Title:</b>	Duopa (carbidopa/levodopa) Enteral suspension		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	12/11/2019, 1/22/2020, 2/4/2021, 1/27/2022, 1/26/2023, 12/07/2023, 01/04/2024		

**Purpose:** To support safe, effective, and appropriate use of Duopa (carbidopa/levodopa).

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Duopa (carbidopa/levodopa) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Duopa (carbidopa/levodopa) will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**

- The patient is 18 years of age and older; AND
- The patient has a diagnosis of advanced Parkinson’s Disease; AND
- The drug is being prescribed by or in consultation with a neurologist or a specialist in movement disorders; AND
- The patient has a presence of complicated motor fluctuations; AND
- The patient is inadequately controlled with optimal medical therapy which includes
  - oral levodopa/carbidopa; AND
  - a dopamine agonist; AND
  - a catechol-O-methyl transferase (COMT) inhibitor; OR
  - a monoamine oxidase B (MAO)-B inhibitor; AND
- The patient experiences 3 hours or more of “off time” on their current drug regimen; AND
- A percutaneous endoscopic gastrostomy with jejunal extension (PEG-J) tube is in place; AND
- Duopa is administered by a CADD-legacy 1400 portable infusion pump;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

***Continuation of Therapy Criteria:***

- The patient is 18 years of age and older; AND
- The patient has a diagnosis of advanced Parkinson’s Disease; AND
- The drug is being prescribed by or in consultation with a neurologist or a specialist in movement disorders; AND
- The patient has a presence of complicated motor fluctuations; AND
- The patient experienced 3 hours or more of “off time” on their previous drug regimen; AND
- Patient is tolerating and responding to medication (stabilization or absence of disease progression) and there continues to be a medical need for the medication.

**Coverage durations:**

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

**Dosage/Administration:**

Indication	Dose	Maximum dose (1 billable unit = 100ml )
Parkinson’s Disease	1 cassette (100ml) per day	3000 billable units every 28 days

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from

tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension

References:

1. Duopa (Prrescribing Information), North Chicago, IL. AbbVie Inc. 2022 March.
2. Olanow CW, Kieburtz K, Odin P, et al; for the LCIG Horizon Study Group. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study. *Lancet*. 2014; 13(2):141-149. PMID 24361112
3. Nyholm D, Odin P, Johansson A, et al. Pharmacokinetics of levodopa, carbidopa, and 3-O-methyldopa following 16- hour jejunal infusion of levodopa-carbidopa intestinal gel in advanced Parkinson's disease patients. *AAPS J*. 2013; 15(2):316-323. PMID 23229334
4. Zibetti M, Merola A, Ricchi V, et al. Long-term duodenal levodopa infusion in Parkinson's disease: a 3-year motor and cognitive follow-up study. *J Neurol*. 2013; 260(1):105-114. PMID 22772358
5. Abbruzzese G, Barone P, Bonuccelli U, et al. Continuous intestinal infusion of levodopa/carbidopa in advanced Parkinson's disease: efficacy, safety and patient selection. *Funct Neurol*. 2012; 27(3):147-154. PMID 23402675
6. Nyholm D, Johansson A, Lennernäs H, et al. Levodopa infusion combined with entacapone or tolcapone in Parkinson disease: a pilot trial. *Eur J Neurol*. 2012; 19(6):820-826. PMID 22136163
7. Nyholm D, Klangemo K, Johansson A. Levodopa/carbidopa intestinal gel infusion long-term therapy in advanced Parkinson's disease. *Eur J Neurol*. 2012; 19(8):1079-1085. PMID 22360705
8. Nyholm D, Nilsson Remahl AI, Dizdar N, et al. Duodenal levodopa infusion monotherapy vs oral polypharmacy in advanced Parkinson disease. *Neurology*. 2005; 64(2):216-223. PMID 15668416
9. Jugel C, Ehlen F, Taskin B, et al. Neuropathy in Parkinson's disease patients with intestinal levodopa infusion versus oral drugs. *PLoS One*. 2013; 8(6):e66639. PMID 23818953