

Policy Title:	Duopa (carbidopa/levodopa) Enteral suspension		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/11/2019, 1/22/20		
Revision Date:	12/11/2019, 1/22/20		

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

Scope: Medicaid, Exchange, 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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

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 (Prescribing Information), North Chicago, IL. AbbVie Inc. 2016 Sept.
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. Jügel 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