Policy Title:	Duopa (carbidopa/levodopa) Enteral suspension		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/11/2019, 1/22/2020, 2/4/2021, 1/27/2022, 1/26/2023, 12/07/2023, 01/04/2024, 04/08/2025, 02/17/2026		

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

Scope: Medicaid, Commercial, Medicare

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.

Summary of Evidence:

Duopa is a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid) indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease. Clinical evidence supports 12 weeks of treatment with Duopa significantly decreased (i.e. improved) mean "Off" time compared with oral immediate-release carbidopa-levodopa by approximately 1.9 hours (p=0.0015) as well as increased (i.e., improved) mean "On" time without troublesome dyskinesia by approximately 1.9 hours (p=0.0059). The most common side effects are nausea, dyskinesia, constipation, peripheral neuropathy, and hallucinations; serious risks also include neuropsychiatric effects, orthostatic hypotension, and impulse control disorders consistent with dopaminergic therapy.

Initial Criteria:

- The member is 18 years of age and older; AND
- The member has a diagnosis of levodopa-responsive advanced Parkinson's Disease with clearly defined "on" periods; AND
- The drug is being prescribed by or in consultation with a neurologist or a specialist in movement disorders; AND
- The member has a presence of complicated motor fluctuations; AND
- The member 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 member experiences "off" periods of at least 3 hours per day 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;
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- The drug continues to be prescribed by or in consultation with a neurologist or a specialist in movement disorders; AND
- The member 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: 12 months
- Continuation of therapy coverage: 12 months

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

Policy Rationale:
Duopa was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Duopa according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 100ml)
Parkinson's Disease	The maximum recommended daily dose is 2000 mg of levodopa or 100 ml (i.e., one cassette per day) administered over 16 hours.	28 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:

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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

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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
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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
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