Policy Title: Duopa (carbidopa/levodopa) Enteral suspension

| Effective Date: | 01/01/2020 |
| Review Date: | 12/11/2019, 1/22/2020, 2/4/2021 |
| Revision Date: | 12/11/2019, 1/22/2020, 2/4/2021 |

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; AND
- 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:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 100ml)</th>
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</thead>
<tbody>
<tr>
<td>Parkinson’s Disease</td>
<td>1 cassette (100ml) per day</td>
<td>3000 billable units every 28 days</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J7340</td>
<td>Carbidopa 5 mg/levodopa 20 mg enteral suspension</td>
</tr>
</tbody>
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References:
1. Duopa (Prescribing Information), North Chicago, IL. AbbVie Inc. 2020 May.