



Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Duopa (carbidopa and levodopa) Enteral Suspension for Parkinson's Disease

Policy Number: HS-291

Original Effective Date: 7/9/2015

**Revised Date(s): 3/3/2016; 1/12/2017;
11/2/2017; 10/4/2018**

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

The U.S. Food and Drug Administration (FDA) approved Duopa (a formula of carbidopa and levodopa) to treat a small subset of patients with advanced Parkinson's disease. Duopa enteral suspension is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.¹ Duopa is an enteral suspension that is dispensed in 100-mL cassette reservoirs that are specifically designed to be connected to the CADD-Legacy® 1400 pump. The pump is required for administration of Duopa. The enteral suspension consists of:²

- **Levodopa** (20 mg/mL), which is the metabolic precursor of dopamine. Levodopa is able to cross the blood-brain barrier, where it is converted to dopamine in the brain. An increase in brain dopamine is believed to be the basis for symptomatic relief in patients with Parkinson's Disease (PD).
- **Carbidopa** (4.63 mg/mL), which inhibits the metabolism of peripheral levodopa, allowing more levodopa to be available for transport into the brain. The co-administration of carbidopa with levodopa increases plasma levels of levodopa and reduces the peripheral effects of levodopa.

The CADD-Legacy® 1400 Pump. The CADD-Legacy® 1400 portable external infusion pump (EIP) delivers the Duopa enteral suspension at a continuous rate for 16 hours. The pump administers the Duopa enteral suspension directly into the jejunum, bypassing the stomach. The gastric emptying rate does not influence the absorption of

Duopa since it is administered by continuous intestinal infusion. Long-term administration of Duopa requires placement of a PEG-J outer transabdominal tube and inner jejunal tube. Prior to PEG-J placement, initiation of treatment may be accomplished short term using a nasojejunal tube. The pump is programmed to deliver individualized patient doses automatically. ²

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Exclusions

Contraindications. Duopa is contraindicated in those who are currently taking or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension. PEG-J placement is contraindicated with lack of trans-illumination and positive needle aspiration test (absolute contraindications), intestinal obstruction, sepsis, active peritonitis, and serious coagulation disorders. Relative contraindications include ascites and neoplastic, inflammatory, and infiltrative diseases of the gastric and abdominal walls.

Coverage

Duopa (carbidopa and levodopa) enteral suspension is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease and **is considered medically necessary** when the member:

- Is levodopa responsive with clearly defined "on" periods; **AND**,
- Has off periods greater than 3 hours per day despite optimization efforts; **AND**,
- Does not have dementia, severe depression, cerebral atrophy, or Hoehn and Yahr stage V Parkinson's.

NOTE: An "off period" is a period of time when Parkinsonian symptoms re-appear because the medication has worn off or is not effective.

CODING

Covered HCPCS Code

- E0781** Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
- J7340** Carbidopa 5 mg/levodopa 20 mg enteral suspension

Covered ICD-10 Code

- G20** Paralysis agitans; parkinsonism or Parkinson's disease: NOS, idiopathic, primary

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Duopa (Carbidopa and Levodopa) Enteral Suspension for Treatment of Parkinson's Disease. Hayes Directory Web site. <http://www.hayesinc.com>. Published August 10, 2016 (reviewed July 17, 2017). Accessed September 13, 2018.
2. FDA approves two treatment options for Parkinson's Disease. Hayes Inc. Web site. <http://www.hayesinc.com>. Published January 19, 2015. Accessed September 13, 2018.
3. Material safety data sheet: Duopa. MSDS Online Web site. <https://msdsmanagement.msdsonline.com/a4c88c26-b80e-4e0c-8326-59699b617f5e/ebinder/29983147/>. Published 2015. Accessed September 13, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
10/4/2018	<ul style="list-style-type: none"> • Approved by MPC. No changes.
1/12/2017	<ul style="list-style-type: none"> • Approved by MPC. Updated J-code to J7340.
3/3/2016	<ul style="list-style-type: none"> • Approved by MPC. Updated 'off period' from 5 hours to 3 hours.
7/9/2015	<ul style="list-style-type: none"> • Approved by MPC. New.