

SPECIALTY GUIDELINE MANAGEMENT

DUOPA (carbidopa and levodopa enteral suspension)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Duopa is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for members who are receiving concomitant treatment with nonselective monoamine oxidase (MAO) inhibitors (e.g., phenelzine, tranylcypromine)

III. CRITERIA FOR INITIAL APPROVAL

Parkinson's disease

Authorization of 6 months may be granted for treatment of motor fluctuations in members with advanced Parkinson's disease when all of the following criteria are met:

- A. Member is levodopa responsive with clearly defined "on" periods; *and*
- B. The member has off periods greater than 3 hours per day despite optimization efforts; *and*
- C. The member must have had an inadequate response or intolerable adverse event with oral carbidopa-levodopa (IR or CR) and one of the following anti-Parkinson agents:
 1. Catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone)
 2. Monoamine oxidase B (MAO)-B inhibitor (e.g., oral selegiline, Azilect)
 3. Dopamine agonists (e.g., pramipexole, ropinirole, Neupro)

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for Parkinson's disease who have demonstrated a positive clinical response to Duopa therapy.

V. REFERENCES

1. Duopa [package insert]. North Chicago, IL: AbbVie, Inc; May 2020.
2. C. Warren Olanow, Karl Keiburtz, Per Odin, et al. Double blind, double dummy, randomized study of continuous intrajejunal infusion of levodopa-carbidopa intestinal gel in advanced Parkinson's disease, *Lancet Neurol.* 2014 February; 13 (2): 141-149.