

Clinical Pharmacy Program Guidelines for Duopa

Program	Prior Authorization
Medication	Duopa (carbidopa and levodopa) enteral suspension
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

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

2. Coverage Criteria:

<p>A. <u>Initial Authorization</u></p> <ol style="list-style-type: none"> 1. Diagnosis of Parkinson's disease <p style="text-align: center;">-AND-</p> 2. Patient is levodopa-responsive <p style="text-align: center;">-AND-</p> 3. Patient experiences disabling “off” periods for a minimum of 3 hours/day <p style="text-align: center;">-AND-</p> 4. Disabling “off” periods occur despite therapy with <u>both</u> of the following: <ol style="list-style-type: none"> (a) Oral levodopa-carbidopa (b) One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT inhibitor [entacapone, tolcapone], MAO-B inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole]) <p style="text-align: center;">-AND-</p> 5. Prescribed by or in consultation with a neurologist <p>Authorization will be issued for 12 months.</p>

B. Reauthorization

1. Documentation of positive clinical response to Duopa therapy

Authorization will be issued for 12 months.

- A. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [2,3]
- B. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of “Off” time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [2,3]
- C. Most patients (89%) were taking at least one concomitant medication for Parkinson's disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [2,3]

3. References:

- 1. Duopa Prescribing Information. AbbVie Inc.,September 2016. .
- 2. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study. Lancet Neurol. 2014;13(2):141-9.

Program	Prior Authorization - Duopa (carbidopa and levodopa) enteral suspension
Change Control	
Date	Change
6/2015	New Policy
9/2016	Updated policy template
9/2017	Annual Review. Updated References.