Prior Authorization
Parkinson’s Disease - Ongentys® (opicapone capsules)

Cigna covers opicapone (Ongentys®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Ongentys. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Ongentys as well as the monitoring required for adverse events and long-term efficacy, approval requires Ongentys to be prescribed by or in consultation with a physician who specializes in the condition being treated.

FDA Indication(s)

1. **Parkinson’s Disease.** Approve for 1 year if the individual meets all of the following criteria (A, B, and C):
   
   A) Individual is currently receiving carbidopa/levodopa therapy; AND
   
   B) Individual meets ONE of the following criteria (i or ii):
      
      i. Individual has tried an entacapone product and meets ONE of the following criteria (a or b):

a) Individual had significant intolerance, according to the prescriber; OR
b) Individual had inadequate efficacy, according to the prescriber; OR
ii. Individual is currently receiving Ongentys; AND
C) Ongentys is prescribed by or in consultation with a neurologist.
D)

Conditions Not Covered

Opicapone (Ongentys®) is considered experimental, investigational or unproven for ANY other use.

Background

Overview
Ongentys, a peripheral, selective and reversible catechol-o-methyltransferase inhibitor, is indicated for adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing “off” episodes.¹

Guidelines
The American Academy of Neurology published guidelines in 2006 on the treatment of Parkinson’s disease with motor fluctuations and dyskinesia.² The guidelines are dated and do not include more recently approved medications, including Ongentys. It is recommended to offer entacapone and rasagiline to reduce “off” time (Level A). Pergolide (withdrawn from the market in 2007 due to risk of valvular fibrosis), pramipexole, ropinirole, and tolcapone (used with caution; requires monitoring for hepatotoxicity) should be considered to reduce “off” time (Level B). Apokyn® (apomorphine hydrochloride injection), cabergoline, and selegiline may be used to reduce “off” time (Level C). According to the guidelines, the available evidence does not establish superiority of one medication over another in reducing “off” time (Level B). Sustained-release levodopa/carbidopa and bromocriptine should not be considered to reduce “off” time (Level C). Amantadine may be used to reduce dyskinesia (Level C).

References


Last Revision Details

| Selected Revision | Parkinson’s Disease. For patients currently receiving Ongentys therapy, criteria was added to allow for continuation without trial of entacapone. For patients with a trial of entacapone, wording of “unacceptable tolerability” was changed to “significant intolerance” and “could not achieve adequate benefit” was changed to “had inadequate efficacy”. | 08/19/2020 |

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