

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	NA

Ongentys (opicapone)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ongentys (opicapone)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Ongentys (opicapone) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Parkinson's disease; **AND**
- II. Individual is using Ongentys concomitantly with carbidopa/levodopa therapy in individuals with hypomobility "off" episodes.
- III. Individual has had a previous trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent.

Preferred agents: entacapone, carbidopa/levodopa/entacapone (Stalevo)

Ongentys (opicapone) may not be approved for:

- I. Individuals with severe hepatic impairment (Child Pugh Class C); **OR**
- II. Individuals with pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; **OR**
- III. Individuals with end-stage renal disease [ESRD] defined as creatinine clearance less than 15 mL/min.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 6, 2020.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Parkinson's Disease in Adults. NICE Guideline [NG71]. National Institute for Health and Care Excellence. Published Date July 2017. Available at: <https://www.nice.org.uk/guidance/ng71>. Accessed on July 6, 2020.
6. Pahwa R, Factor SA, Lyons KE, et al.; Quality Standards Subcommittee of the American Academy of Neurology. Practice Parameter: treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Neurology. 2006; 66(7):983-995. Accessed July 6, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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