MEDICAL MUTUAL®

Drug Policy

Policy:	Ongentys (Opicapone) capsules	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Ongentys, a peripheral, selective and reversible catechol-o-methyltransferase (COMT) inhibitor, is indicated for adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes. ***Mechanism of Action:*** When decarboxylation of levodopa is prevented by carbidopa, COMT becomes the major metabolizing enzyme for levodopa, catalyzing its metabolism. ***Dosing/Administration:*** The recommended dose is 50 mg administered orally once daily (QD) at bedtime. Patients should not eat food for 1 hour before and for at least 1 hour after intake of Ongentys. Dose modifications. In patients with moderate hepatic impairment (Child-Pugh B), the recommended dose is 25 mg administered orally QD at bedtime. ***Availability/Storage:*** Ongentys is available as 25 mg and 50 mg capsules.

POLICY STATEMENT

This policy involves the use of Ongentys. Prior authorization is recommended for pharmacy benefit coverage of Ongentys. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ongentys as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ongentys be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ongentys is recommended in those who meet the following criteria:

1. Parkinson's Disease

Criteria. *Patient must meet the following criteria (A, B, C, D, E, and F)*

A. The patient experiences hypomobility or "off" episodes; AND
B. The patient is receiving Ongentys in combination with levodopa/carbidopa: AND
C. Patient is 18 years of age or older; AND
D. The patient is not concurrently taking a non-selective monoamine oxidase inhibitor (MAOI) (such as: phenelzine, isocarboxazid, etc.); AND

E. The patient does not have pheochromocytoma, paraganglioma, or catacholamine secreting neoplasms; AND
F. Patient meets ONE of the following criteria (a or b):
    a. Patient has tried an entacapone product and meets ONE of the following criteria (i or ii):
        i. Patient had significant intolerance, according to the prescriber; OR
        ii. Patient had inadequate efficacy, according to the prescriber; OR
    b. Patient is currently receiving Ongentys; AND
G. Ongentys is being prescribed by, or in consultation with, a neurologist or prescriber specializing in the treatment of Parkinson's disease.

2. Patient has been started on Ongentys
Criteria. *Patient must meet the following criteria (A, B, and C)*

A. Patient is 18 years of age or older; AND
B. The patient is diagnosed with episodes of Hypomobility ("off" episodes) associated with Parkinson's disease; AND
C. The patient has experienced a positive clinical response to therapy; AND
D. Ongentys is being prescribed by, or in consultation with, a neurologist or prescriber specializing in the treatment of Parkinson's disease

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ongentys has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Ongentys® capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences; May 2020.
2. Ferreira JJ, Lees A, Rocha JF, et al. Opicapone as an adjunct to levodopa in patients with Parkinson's disease and end-of-dose motor fluctuations: a randomised, double-blind, controlled trial. *Lancet Neurol.* 2016;15:154-165.
3. Ferreira JJ, Lees AJ, Poewe W, et al. Effectiveness of opicapone and switching from entacapone in fluctuating Parkinson disease. *Neurology*. 2018;90(21):e1849-e1857.
4. Lees AJ, Ferreira J, Rascol O, et al. Opicapone as adjunct to levodopa therapy in patients with Parkinson disease and motor fluctuations: a randomized clinical trial. *JAMA Neurol*. 2017;74:197-206.
5. Connolly BS, Lang AE. Pharmacological treatment of Parkinson disease. A review. *JAMA*. 2014;311(16):1670-1683.
6. National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's disease information page. Last updated: April 29, 2020. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Parkinsons-Disease-Information-Page. Accessed on May 13, 2020.
7. Pahwa R, Factor SA, Lyons KE, et al. Practice parameter: treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the quality standards subcommittee of the American Academy of Neurology. *Neurology*. 2006;66:983-995.