

Pharmacy Policy Bulletin: J-1005 Omentys (opicapone) – Commercial and Healthcare Reform	
Number: J-1005	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Other Managed Drugs = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-1005-008	Original Date: 06/03/2020
Effective Date: 07/18/2025	Review Date: 06/25/2025

Drugs Product(s):	Omentys (opicapone)
FDA-Approved Indication(s):	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease (PD) experiencing “off” episodes.

Background:	- Omentys (opicapone) exerts its effects as a selective, reversible catechol-O-methyltransferase (COMT) inhibitor. - Carbidopa is often combined with levodopa to prevent decarboxylation. When these two agents are used in combination, the metabolism of levodopa is primarily mediated by the COMT enzyme. - Dystonia occurs in PD typically after several years of treatment with a dopamine agonist (for example, levodopa). Changes in motor symptoms occur as fluctuations between treatment periods and involve “on” periods, in which patients experience a positive response to levodopa therapy, and “off” periods, in which levodopa response wears off. - To treat motor fluctuations including “off” episodes, The International Parkinson and Movement Disorder Society (IPMDS) recommends adjusting the dosing frequency of levodopa to a shorter time interval, improving absorption by taking levodopa on an empty stomach, and treating constipation to improve gastrointestinal transit. - The guidelines also recommend addressing “off” episodes with adjunctive medications by evaluating side effect profiles and individual patient characteristics as well as cost and availability. First-line treatments are usually oral (or transdermal) agents followed by parenteral and surgical techniques for more advanced patients. All non-ergot dopamine agonists are clinically useful for reducing motor fluctuations. Enhancing levodopa duration with enzyme inhibition using COMT and/or MAO-B inhibition remains an effective approach for reducing motor fluctuations. - The 2018 IPMDS guidelines recommend the following drugs as clinically useful or possibly useful for treatments to prevent/delay motor fluctuations:
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	pramipexole, ropinirole, cabergoline, and bromocriptine. For treatment of motor fluctuations, the following drugs are considered clinically useful or possibly useful: pramipexole, ropinirole, Neupro, apomorphine, bromocriptine, cabergoline, levodopa/carbidopa, entacapone, tolcapone, Ongentys, rasagiline, zonisamide, Xadago, and Nourianz. While selegiline has been deemed investigational in the guidelines for treating motor fluctuations, it is recommended as clinically useful for early PD requiring symptomatic therapy. • Prescribing Considerations: ○ Ongentys should not be used in combination with other MAO-B inhibitors. ○ Ongentys should not be used as monotherapy for the treatment of PD.
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Approval Criteria

I. Initial Authorization

When a benefit, coverage of Ongentys may be approved when all of the following criteria are met **(A. through E.)**:

- A. The member has a diagnosis of Parkinson's disease (ICD-10: G20).
- B. The member will be using Ongentys as an adjunct to carbidopa/levodopa.
- C. The member is experiencing "off" episodes between levodopa/carbidopa doses.
- D. The member has experienced therapeutic failure, contraindication, or intolerance to the plan preferred product, generic entacapone.
- E. The member has experienced therapeutic failure or intolerance to two (2) or contraindication to all of the following plan-preferred products **(1. through 4.)**:
 1. rasagiline
 2. pramipexole
 3. ropinirole
 4. selegiline

II. Reauthorization

When a benefit, reauthorization of Ongentys may be approved when all of the following criteria are met **(A. and B.)**:

- A. The prescriber attests that the member has experienced positive clinical response to therapy.
- B. The member is using Ongentys as an adjunct to carbidopa/levodopa.

- III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I. Coverage of the drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Ongentys [package insert]. San Diego, CA: Neurocrine Biosciences Inc.; February 2025.
2. Liang TW, Tarsy D. Medical management of motor fluctuations and dyskinesia in Parkinson disease. Available at: <https://www.uptodate.com/contents/medical-management-of-motor-fluctuations-and-dyskinesia-in-parkinson-disease>. Accessed May 20, 2025.
3. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2012
4. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018;33(8):1248-1266.
5. Pringsheim T, et al.; Guideline Subcommittee of the AAN. Dopaminergic Therapy for Motor Symptoms in Early Parkinson Disease Practice Guideline Summary: A Report of the AAN Guideline Subcommittee. *Neurology*. 2021 Nov 16;97(20):942-957.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.