

## Clinical Policy: Opicapone (Ongentys)

Reference Number: ERX.NPA.144

Effective Date: 09.01.20

Last Review Date: 08.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

### Description

Opicapone (Ongentys<sup>®</sup>) is a catechol-O-methyltransferase (COMT) inhibitor.

### FDA Approved Indication(s)

Ongentys is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions<sup>™</sup> that Ongentys is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Parkinson's Disease (must meet all):

1. Diagnosis of PD;
2. Prescribed by or in consultation with an neurologist;
3. Age  $\geq$  18 years;
4. Member is experiencing "off" time (*see Appendix D*) on levodopa/carbidopa therapy;
5. Failure of two of the following adjunct drugs prescribed in combination with levodopa/carbidopa, each from different classes, unless contraindicated or clinically significant adverse effects are experienced:\*
  - a. MAO-B inhibitor: rasagiline;
  - b. COMT inhibitor: entacapone (Comtan<sup>®</sup>/Stalevo<sup>®</sup>), tolcapone;
  - c. Dopamine agonist: ropinirole/ropinirole ER, pramipexole/pramipexole ER;
6. Prescribed in combination with levodopa/carbidopa;
7. Dose does not exceed 50 mg (1 capsule) per day.

**Approval duration: 6 months**

##### B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### II. Continued Therapy

##### A. Parkinson's Disease (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 50 mg (1 capsule) per day.

**Approval duration: 12 months**

**A. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

COMT: catechol-O-methyl transferase

FDA: Food and Drug Administration

MAO-B: monoamine oxidase type B

PD: Parkinson's disease

*Appendix B: Therapeutic Alternatives*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>COMT Inhibitors</b>		
carbidopa/levodopa/entacapone (Stalevo <sup>®</sup> )	PO: Dose should be individualized based on therapeutic response; doses may be adjusted by changing strength or adjusting interval. Fractionated doses are not recommended and only 1 tablet should be given at each dosing interval.	1,200 mg/day (divided doses)
entacapone (Comtan <sup>®</sup> )	PO: 200 mg with each dose of levodopa/carbidopa	1,600 mg/day (divided doses)
tolcapone (Tasmar <sup>®</sup> )	PO: 100 mg 3 times daily, as adjunct to levodopa/carbidopa	300 mg/day
<b>MAO-B Inhibitors</b>		
rasagiline (Azilect <sup>®</sup> )	PO: Monotherapy or adjunctive therapy (not including levodopa): 1 mg once daily. Adjunctive therapy with levodopa: Initial: 0.5 mg once daily; may increase to 1 mg once daily based on response and tolerability.	1 mg/day
<b>Dopamine Agonists</b>		
pramipexole (Mirapex <sup>®</sup> )	PO: Initial dose: 0.125 mg 3 times daily, increase gradually every 5 to 7 days; maintenance (usual): 0.5 to 1.5 mg 3 times daily	4.5 mg/day (divided doses)
pramipexole ER (Mirapex <sup>®</sup> ER)	PO: Initial dose: 0.375 mg once daily; increase gradually not more frequently than every 5 to 7 days to 0.75 mg once daily and then, if necessary, by 0.75 mg per dose	4.5 mg/day
ropinirole (Requip <sup>®</sup> )	PO: Recommended starting dose: 0.25 mg 3 times/day. Based on individual patient response, the dosage should be titrated with weekly increments: Week 1: 0.25 mg 3 times/day; total daily dose: 0.75 mg; week 2: 0.5 mg 3 times/day; total daily dose: 1.5 mg; week 3: 0.75 mg 3 times/day; total daily dose: 2.25 mg; week 4: 1 mg 3 times/day; total daily dose: 3 mg. After week 4, if necessary, daily dosage may be increased by 1.5 mg/day on a weekly basis up to a dose of 9 mg/day,	24 mg/day (divided doses)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	and then by up to 3 mg/day weekly to a total of 24 mg/day.	
ropinirole ER (Requip® ER)	PO: Initial dose: 2 mg once daily for 1 to 2 weeks, followed by increases of 2 mg/day at weekly or longer intervals based on therapeutic response and tolerability	24 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

**Appendix C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Concomitant use of non-selective MAO inhibitors.
  - History of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.
- Boxed warning(s): none reported

**Appendix D: General Information**

- Off time/episodes represent a return of PD symptoms (bradykinesia, rest tremor or rigidity) when the L-dopa treatment effect wears off after each dosing interval.
- PD symptoms, resulting from too little levodopa (L-dopa), are in contrast with dyskinesia which typically results from too much L-dopa. The alterations between “on” time (the time when PD symptoms are successfully suppressed by L-dopa) and “off” time is known as “motor fluctuations”.
- The addition of carbidopa to L-dopa prevents conversion of L-dopa to dopamine in the systemic circulation and liver.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
PD	50 mg PO QD at bedtime	50 mg/day

**VI. Product Availability**

Capsules: 25 mg, 50 mg

**VII. References**

1. Ongentys Prescribing Information. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212489s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212489s000lbl.pdf). Accessed May 11, 2020.
2. Pahwa MD, Factor SA, Lyons KE, et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review): [RETIRED] Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2006 Apr;66:983-995.
3. 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 Aug;33(8):1248-1266.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 11, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.02.20	08.20

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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