

Initial Prior Authorization

Ongentys

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ongentys	opicapone

Indications

FDA-approved Indications

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

Coverage Criteria

Parkinson's Disease (PD)

Authorization may be granted when the requested drug is being prescribed as adjunctive treatment to levodopa/carbidopa in a patient with Parkinson's disease (PD) experiencing "off" episodes when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response to a trial of generic carbidopa/levodopa/entacapone OR generic entacapone used in combination with a generic levodopa/carbidopa product

- The patient has experienced an intolerance to generic carbidopa/levodopa/entacapone OR generic entacapone used in combination with a generic levodopa/carbidopa product
- The patient has a contraindication that would prohibit a trial of generic carbidopa/levodopa/entacapone OR generic entacapone used in combination with a generic levodopa/carbidopa product

Duration of Approval (DOA)

- 5464-A: DOA: 12 months

References

1. Ongentys [package insert]. Bridgewater, NJ: Amneal Specialty, a division of Amneal Pharmaceuticals LLC.; December 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed August 5, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/05/2024).
4. Greenwood J, Pham H, Rey J. Opicapone: a third generation COMT inhibitor. Clin Park Relat Disord 2021(4):100083.

Document History

Written by: UM Development (DRS)

Date Written: 07/2022

Revised: 08/2022 (no clinical changes), VLS 08/2023 (no clinical changes), 08/2024 (no clinical changes)

Reviewed: Medical Affairs (CHART) 07/21/2022, 08/25/2022, 08/24/2023, 08/29/2024

External Review: 10/2022 (FYI), 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed as adjunctive treatment to levodopa/carbidopa in a patient with Parkinson's disease (PD) experiencing "off" episodes? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response to a trial of generic carbidopa/levodopa/entacapone or generic entacapone used in	Yes	No

combination with a generic levodopa/carbidopa product?
[If Yes, then no further questions. If No, then go to 3.]

3	Has the patient experienced an intolerance to generic carbidopa/levodopa/entacapone or generic entacapone used in combination with a generic levodopa/carbidopa product? [If Yes, then no further questions. If No, then go to 4.]	Yes No
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4	Does the patient have a contraindication that would prohibit a trial of generic carbidopa/levodopa/entacapone or generic entacapone used in combination with a generic levodopa/carbidopa product? [No further questions]	Yes No
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Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for "off" episodes in patients with Parkinson's disease (PD) being treated with levodopa/carbidopa. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Approve, 12 Months	Go to 3	
3.	Approve, 12 Months	Go to 4	
4.	Approve, 12 Months	Deny	<p>Your plan only covers this drug if you have tried generic carbidopa/levodopa/entacapone or generic entacapone used in combination with a generic levodopa/carbidopa, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to</p>

Reference number(s)
5464-A

			<p>take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step therapy]</p>
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