

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

| Reference number(s) |
|---------------------|
| 5464-A |

- 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.