

Policy Name:	Ongentys (opicapone)	Policy #:	2802P
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Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Ongentys (opicapone).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Ongentys under the pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of Parkinson's disease
- 1.2 Age 18 years or older
- 1.3 Ordered by or in consultation with a neurologist (central nervous system doctor)
- 1.4 Documentation that member is experiencing "off" episodes (return of Parkinson's symptoms) while receiving a carbidopa/levodopa regimen where attempts have been made to adjust the carbidopa/levodopa dose and/or formulation in order to manage symptoms without success
- 1.5 Member will continue receiving carbidopa/levodopa in combination with Ongentys
- 1.6 Member has had previous inadequate response, intolerance, or contraindication to at least two different classes of medications for the treatment of Parkinson's disease
 - Monoamine oxidase type B inhibitors, such as rasagiline or selegiline
 - Dopamine agonists, such as ropinirole or pramipexole
 - Catechol-O-methyl transferase inhibitors, such as entacapone

2. Approval Period

- 2.1 Initial Approval: 12 months
- 2.2 Subsequent Approvals: 12 months with documented stabilization of disease or absence of disease progression

CPT Codes

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HCPCS Codes

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References

1. Ongentys (opicapone) [prescribing information]. San Diego, CA: Neurocrine Biosciences Inc; April 2020.
2. 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(2):197-206.
3. Fox S, Katzenschlager R, Lim S, et al. International Parkinson and Movement Disorder Society Evidence-Based Medicine Review: Update on Treatments for the Motor Symptoms of

Parkinson's Disease.

4. Pringsheim T, Day G, Smith D, et al on behalf of the 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. Nov 2021, 97 (20) 942-957.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.