



Drug Coverage Policy

Effective Date06/15/2025

Coverage Policy Number.....IP0532

Policy Title.....Ongentys

Parkinson's Disease – Ongentys

- Ongentys® (opicapone capsules – Neurocrine Biosciences)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Ongentys, a peripheral, selective, and reversible catechol-o-methyltransferase (COMT) inhibitor, is indicated for adjunctive treatment to levodopa/carbidopa in patients with **Parkinson's disease** experiencing "off" episodes.¹

Guidelines

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment of motor symptoms of Parkinson's disease (2018).² The review categorically divides treatment recommendations by Parkinson's disease characteristics. Ongentys is noted to be efficacious and clinically useful in treatment of motor fluctuations.

Coverage Policy

Policy Statement

Prior Authorization is required for prescription benefit coverage of Ongentys. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ongentys as well as the monitoring required for adverse events and long-term efficacy, approval requires Ongentys to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Ongentys is considered medically necessary when the following criteria are met:

FDA-Approved Indication

- 1. Parkinson's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
 - A)** Patient is currently receiving carbidopa/levodopa therapy; AND
 - B)** The medication is prescribed by or in consultation with a neurologist; AND
 - C)** Preferred product criteria are met for the product(s) as listed in the below table(s):

Employer Plans:

Product	Criteria
Ongentys (opicapone capsules)	ONE of the following: <ol style="list-style-type: none">1. Failure, contraindication, or intolerance to entacapone (Comtan generic)2. Currently receiving Ongentys

Individual and Family Plans:

Product	Criteria
Ongentys (opicapone capsules)	ONE of the following: <ol style="list-style-type: none">1. Failure, contraindication, or intolerance to entacapone (Comtan generic)2. Currently receiving Ongentys

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Ongentys for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Ongentys® capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences; February 2025.
2. 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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Parkinson's disease: Updated coverage policy title from <i>Opicapone</i> to <i>Parkinson's Disease – Ongentys</i> Removed criterion requiring patient experience "off" episodes.	07/01/2024
Annual Review	No criteria changes	06/15/2025

The policy effective date is in force until updated or retired.

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