

# Drug and Biologic Coverage Policy



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## Opicapone

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### Related Coverage Resources

[Quantity Limitations](#)

#### 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. 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

This policy supports medical necessity review for opicapone (**Ongentys**<sup>®</sup>).

Coverage for opicapone (Ongentys) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

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

### Initial Approval Criteria

**Opicapone (Ongentys) is considered medically necessary for the treatment of Parkinson's disease when the individual meets ALL of the following criteria:**

1. Experiencing "off" episodes (for example, end-of-dose weaning off muscle stiffness, slow movements, or difficulty starting movements)
2. Currently receiving levodopa-based treatment

3. Medication is prescribed by, or in consultation with, a neurologist
4. **ONE** of the following (a or b):
  - a. Documentation of failure, contraindication, or intolerance to entacapone (generic for Comtan)
  - b. 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.

## Continuation of Therapy

Continuation of opicapone (Ongentys) is considered medically necessary for Parkinson's disease when initial criteria are met AND beneficial response is demonstrated.

## Authorization Duration

Initial approval duration: up to 12 months  
Reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Background

### 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.<sup>1</sup>

### Guidelines

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

## References

1. Ongentys® capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences; May 2020.
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.

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