



## Drug Coverage Policy

Effective Date ..... 6/15/2025  
Coverage Policy Number ..... IP0525  
Policy Title ..... Zelapar

### Parkinson's Disease – Zelapar

- Zelapar® (selegiline orally disintegrating tablets – Bausch Health)

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#### 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.

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Zelapar, an irreversible inhibitor of monoamine oxidase, is indicated in patients with **Parkinson's disease** as an adjunct to levodopa/carbidopa among patients who exhibit deterioration in the quality of their response to this therapy.<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. Zelapar is noted to have insufficient evidence and be investigational for treatment of motor fluctuations.

## Coverage Policy

### POLICY STATEMENT

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

### FDA-Approved Indication

**Zelapar is considered medically necessary when the following are met:**

- 1. Parkinson's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
  - A. Patient is experiencing "off" episodes; AND  
Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
  - B. Patient is currently receiving carbidopa/levodopa therapy; AND
  - C. Patient has tried one of oral selegiline tablets, selegiline capsules, or rasagiline tablets and meets ONE of the following (i or ii):
    - i. Patient had significant intolerance, according to the prescriber; OR
    - ii. Patient has difficulty swallowing tablets or capsules; AND
  - D. Zelapar is prescribed by, or in consultation with, a neurologist

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.

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

## References

1. Zelapar® orally disintegrating tablets [prescribing information] Bridgewater, NJ: Bausch Health; June 2021.
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	<b>Updated title from "Selegiline" to "Parkinson's Disease – Zelapar"</b>	6/15/2025

	<p><b>Parkinson's Disease:</b> Examples of evidence of "off" episodes were moved to a Note.</p> <p><b>Updated from</b> "Experiencing "off" episodes" <b>to</b> "Patient is experiencing "off" episodes"</p> <p><b>Updated from</b> "Currently receiving levodopa-based treatment" <b>to</b> "Patient is currently receiving carbidopa/levodopa therapy"</p> <p><b>Updated from</b> "Documentation of ONE of the following: i. Documentation of failure, contraindication, or intolerance, to ONE of the following: rasagiline tablets or selegiline tablets; ii. Inability to swallow tablets" <b>to</b> "Patient has tried one of oral selegiline tablets, selegiline capsules, or rasagiline tablets and meets ONE of the following (i <u>or</u> ii): i. Patient had significant intolerance, according to the prescriber; OR ii Patient has difficulty swallowing tablets or capsules"</p>	
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The policy effective date is in force until updated or retired.

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