

Drug and Biologic Coverage Policy



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Selegiline

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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. 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 selegiline orally disintegrating tablets (Zelapar®).

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

Medical Necessity Criteria

Selegiline orally disintegrating tablet (Zelapar) is considered medically necessary when the following are met:

Parkinson's Disease. Individual meets **ALL** of the following criteria:

- A. Experiencing "off" episodes
- B. Currently receiving levodopa-based treatment
- C. Medication is prescribed by, or in consultation with, a neurologist
- D. 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

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.

Reauthorization Criteria

Continuation of Selegiline orally disintegrating tablet (Zelapar) is considered medically necessary for Parkinson's Disease when the above medical necessity criteria are met AND there is documentation of beneficial response.

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

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.¹

Guidelines

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).² 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.

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.

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