Cigna National Formulary Coverage Policy

Prior Authorization
Parkinson's Disease – Zelapar® (selegiline orally disintegrating tablets)

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Product Identifier(s)

Effective through 12/31/2022: 72324
Effective 1/1/2023: 109242

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.

National Formulary Medical Necessity

Cigna covers selegiline hydrochloride (Zelapar®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended 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 individuals 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 Indication(s)

1. **Parkinson's Disease.** Approve for 1 year if the individual meets all of the following criteria (A, B, C, and D):
   - **A)** Individual is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **B)** Individual is currently receiving carbidopa/levodopa therapy; AND

C) Individual has tried one of the oral selegiline tablets, selegiline capsules, or rasagiline tablets and meets ONE of the following criteria (i or ii):
   i. Individual had significant intolerance, according to the prescriber; OR
   ii. Individual has difficulty swallowing tablets or capsules; AND

D) Zelapar is being prescribed by, or in consultation with, a neurologist.

Conditions Not Covered

Selegiline hydrochloride (Zelapar®) is considered experimental, investigational or unproven for ANY other use.

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	09/14/2022