



Effective Date..... 3/1/2023

Next Review Date..... 3/1/2024

Step Therapy
Parkinson’s Disease – Monoamine Oxidase Type B Inhibitors

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107822

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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.

National Formulary Medical Necessity

Drugs Affected

- Azilect® (rasagiline tablets, generic)
• Selegiline capsules and tablets (generic only)
• Xadago® (safinamide mesylate tablets)

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. Zelapar® (selegiline orally disintegrating tablets) does not require Step Therapy for coverage. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic selegiline tablets and capsules, generic rasagiline tablets

Step 2: Azilect, Xadago

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Azilect, oral selegiline products, and Xadago are monoamine oxidase type B (MAO-B) inhibitors and have similar indications for the **treatment of Parkinson's disease**.¹⁻³ Azilect is indicated for the treatment of Parkinson's disease. Selegiline tablets and capsules are indicated as adjuncts in the management of Parkinsonian patients being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy. Xadago is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).⁴ The review categorically divides treatment recommendations by Parkinson's disease characteristics. Azilect and selegiline are treatments considered to be efficacious and clinically useful for symptomatic monotherapy. For the treatment of motor fluctuations, Azilect and Xadago are noted to be efficacious and clinically useful while selegiline is considered efficacious and possibly useful.

References

1. Azilect® tablets [prescribing information]. North Wales, PA: Teva; June 2020.
2. Selegiline capsules and tablets [prescribing information]. Weston, FL: Apotex; November 2018.
3. Xadago® tablets [prescribing information]. Louisville, KY: US WorldMeds; October 2022.
4. 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.	01/18/2023

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