Clinical Policy: Rasagiline (Azilect)

Reference Number: HIM.PA.89
Effective Date: 12.14
Last Review Date: 08.26
Line of Business: HIM/ICHRA

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Rasagiline (Azilect®) is a monoamine oxidase (MAO)-B inhibitor (MAOI).

FDA Approved Indication(s)

Azilect is indicated for the treatment of Parkinson's disease (PD).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that rasagiline and Azilect is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Parkinson's Disease (must meet all)**:**

1. Diagnosis of PD;
2. Age ≥ 18 years;
3. Failure of selegiline at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;*
   * *For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
4. If request is for brand Azilect, member must use generic rasagiline, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed both of the following (a and b):
   a. 1 mg per day;
   b. 1 tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (health insurance marketplace/ICHRA), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (health insurance marketplace/ICHRA), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA.

II. Continued Therapy

A. Parkinson's Disease (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 1 mg per day;
   b. 1 tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (health insurance marketplace/ICHRA), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (health insurance marketplace/ICHRA), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace/ICHRA or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
MAO: monoamine oxidase
MAOI: monoamine oxidase inhibitor
PD: Parkinson's disease

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
selegiline	5 mg PO BID	10 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): concomitant use of meperidine, tramadol, methadone, propoxyphene dextromethorphan, St. John's wort, cyclobenzaprine, or another (selective or non-selective) MAO inhibitor
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Monotherapy or as adjunct therapy without levodopa	1 mg PO QD	1 mg/day
Adjunct therapy with levodopa ± other PD drugs (e.g., dopamine agonist, amantadine, anticholinergic)	0.5-1 mg PO QD	1 mg/day

VI. Product Availability
Tablets: 0.5 mg, 1 mg

VII. References
1. Azilect Prescribing Information. North Wales, PA: Teva Pharmaceuticals; June 2020. Available at: http://www.azilect.com/. Accessed May 27, 2026.
2. Selegiline Drug Monograph. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com. Accessed May 27, 2026.
3. Fox SH, Katzenschlager R, Lim S, et al. International Parkinson and Movement Disorder Society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. Movement Disorders; 2018. Published online in Wiley Online Library. DOI: 10.1002/mds.27372.
4. Pringsheim T, Day GS, Smith DB, et al. Dopaminergic therapy for motor symptoms in early Parkinson disease practice guideline summary: a report of the AAN guideline subcommittee. Neurology 2021;97:942-957.
5. De Bie R, Katzenschlager R, Swinnen B, et al. Update on treatments for Parkinson's disease motor fluctuations – An international Parkinson and movement disorder society evidence-based medicine review. Movement Disorders 2025;(40)5:776-794.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2022 annual review: no significant changes; added that request is for generic formulation; references reviewed and updated.	03.22.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.11.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.20.23	08.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.13.24	08.24
3Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	04.23.25	08.25
3Q 2026 annual review: no significant changes; added ICHRA line of business; references reviewed and updated.	05.25.26	08.26