Clinical Policy: Rasagiline (Azilect)

Reference Number: HIM.PA.89
Effective Date: 12.14
Last Review Date: 08.21
Line of Business: HIM

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 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;
4. Dose does not exceed 1 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

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 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 (Eldepryl®)	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 March 23, 2021.
2. Selegiline Drug Monograph. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com. Accessed March 23, 2021.
3. Suchowesky O, Gronseth G, Perlmutter J, et al. Practice Parameter: Neuroprotective strategies and alternative therapies for Parkinson disease (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2006; 66(7).
4. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: age limit added; no significant changes; references reviewed and updated.	04.30.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.01.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.27.20	08.20
3Q 2021 annual review: no significant changes; removed Zelapar as a therapeutic alternative as it is NF on the Ambetter core formulary; references revised from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	03.23.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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