Clinical Policy: Rivastigmine (Exelon)

Reference Number: IL.ERX.PMN.101
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

Description

Rivastigmine, as rivastigmine tartrate (Exelon® capsules for oral use) and rivastigmine transdermal system (Exelon® Patch), is an acetylcholinesterase inhibitor.

FDA Approved Indication(s)

Exelon is indicated for treatment of

- Mild to moderate dementia of the Alzheimer's type (AD)*
  **Exelon patch is also indicated for treatment of severe AD.*
- Mild to moderate dementia associated with Parkinson's disease (PDD)

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Exelon is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Alzheimer's Dementia (must meet all)**:**

1. Diagnosis of AD;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b):
   a. Failure of ≥ 3 month trial of donepezil at doses ≥ 10 mg per day unless contraindicated or clinically significant adverse effects are experienced;
   b. If member cannot take donepezil due to intolerance or contraindication(s), failure of ≥ 3 month trial of memantine at doses ≥ 20 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 12 mg per day (oral) or 13.3 mg per 24 hours (transdermal).

Approval duration: 12 months

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

1. Diagnosis of PDD;
2. Age ≥ 18 years;
3. Failure of ≥ 3 month trial of donepezil at doses ≥ 10 mg per day unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 12 mg per day (oral) or 13.3 mg per 24 hours (transdermal).

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met all initial approval criteria;
2. If request is for a dose increase, new dose does not exceed 12 mg per day (oral) or 13.3 mg per 24 hours (transdermal).

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy;
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AD: Alzheimer's dementia
FDA: Food and Drug Administration
PDD: Parkinson's disease dementia
PDL: preferred drug list

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
donepezil (Aricept®)	AD: 5 mg PO QD titrated up to 23 mg PO QD PDD: 5 mg PO QD titrated up to 10 mg PO QD	AD: 23 mg/day PDD: 10 mg/day
memantine (Namenda®, Namenda® XR)	AD (Namenda): 5 mg PO QD titrated up to 10 mg PO BID AD (Namenda XR): 7 mg PO QD titrated to 28 mg PO QD	AD (Namenda): 20 mg/day AD (Namenda XR): 28 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): Known hypersensitivity to rivastigmine, other carbamate derivatives or other components of the formulation. History of application site reaction with rivastigmine transdermal patch suggestive of allergic contact dermatitis, in the absence of negative allergy testing.
- Boxed warning(s): None reported.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AD	Patch: 9.5 mg/24 hours or 13.3 mg/24 hours once daily Capsule: 1.5 to 6 mg twice daily	Patch: 13.3 mg/24 hours transdermally Capsule: 12 mg/day

Indication	Dosing Regimen	Maximum Dose
PDD	Patch: 9.5 mg/24 hours or 13.3 mg/24 hours once daily Capsule: 1.5 to 6 mg twice daily	Patch: 13.3 mg/24 hours transdermally Capsule: 12 mg/day

VI. Product Availability

- Capsules: 1.5 mg, 3 mg, 4.5 mg, and 6 mg.
- Patches: 4.6 mg/24 hours, 9.5 mg/24 hours, and 13.3 mg/24 hours.

VII. References

1. Exelon Patch Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2016. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exelonpatch.pdf. Accessed November 6, 2018.
2. Exelon. Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2016. Available at: https://dailymed.nlm.nih.gov/. Accessed November 6, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at https://www.clinicalpharmacology-ip.com/ Accessed November 6, 2018.
4. Rolinski M, Fox C, Maidment I, McShane R. Cholinesterase inhibitors for dementia with Lewy bodies, Parkinson's disease dementia and cognitive impairment in Parkinson's disease. Cochrane Database of Systematic Reviews. 2012, Issue 3. Art. No.: CD006504. www.cochranelibrary.com.
5. Qaseem A, Snow V, Cross JT, Forciea MA, Hopkins R, Shekelle P, et al. Current Pharmacologic Treatment of Dementia: A Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians. Ann Intern Med. 2008; 148:370-378.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.