Clinical Policy: Rivastigmine (Exelon)

Reference Number: CP.PMN.101
Effective Date: 03.01.17
Last Review Date: 02.25
Line of Business: 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)*
- Mild to moderate dementia associated with Parkinson's disease (PDD)

**Exelon patch is also indicated for treatment of severe AD.*

Policy/Criteria

Provider must submit documentation (including 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 Exelon and rivastigmine are **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 or galantamine 24 mg per day;
   b. Both of the following (i and ii):
      i. Member has intolerance or contraindication to both donepezil and galantamine;
      ii. Failure of ≥ 3 month trial of memantine at doses ≥ 20 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. If Exelon patch is requested, member must use generic rivastigmine patches, unless contraindicated or clinically adverse effects are experienced;
5. Dose does not exceed one of the following (a or b):
   a. Oral, both of the following (i and ii):
      i. 12 mg per day;
      ii. 2 capsules per day;
   b. Transdermal: 13.3 mg (1 patch) per 24 hours.

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. If Exelon patch is requested, member must use generic rivastigmine patches, unless contraindicated or clinically adverse effects are experienced;
5. Dose does not exceed one of the following (a or b):
   a. Oral, both of the following (i and ii):
      i. 12 mg per day;
      ii. 2 capsules per day;
   b. Transdermal: 13.3 mg (1 patch) per 24 hours.

Approval duration: 12 months

C. 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 PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; 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: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (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);*
3. If Exelon patch is requested, member must use generic rivastigmine patches, unless contraindicated or clinically adverse effects are experienced;
2. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Oral, both of the following (i and ii):
      i. 12 mg per day;
      ii. 2 capsules per day;
   b. Transdermal: 13.3 mg (1 patch) per 24 hours.

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 PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; 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: CP.PMN.53 for Medicaid.

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 – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AD: Alzheimer's dementia
PDD: Parkinson's disease dementia
FDA: Food and Drug Administration

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
galantamine (Razadyne®)	AD (Razadyne): 4 mg PO BID titrated up to 12 mg PO BID AD (Razadyne ER): 8 mg PO QD titrated up to 24 mg PO QD	AD: 24 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 QD Oral formulations: • Initial dose: initiate treatment with 1.5 mg PO BID • Dose titration: after a minimum of 2 weeks, if tolerated, increase dose to 3 mg PO BID and further to 4.5 mg PO BID and 6 mg PO BID if tolerate with a minimum of 2 weeks at each dose	Patch: 13.3 mg/24 hours transdermally Oral formulations: 12 mg/day
PDD	Patch: 9.5 mg/24 hours or 13.3 mg/24 hours QD Oral formulations: • Initial dose: initiate treatment with 1.5 mg PO BID • Dose titration: after a minimum of 4 weeks, if tolerated, increase dose to 3 mg PO BID and further to 4.5 mg PO BID and 6 mg PO BID if tolerate with a minimum of 4 weeks at each dose	Patch: 13.3 mg/24 hours transdermally Oral formulations: 12 mg/day

VI. Product Availability

- Generic rivastigmine capsules: 1.5 mg, 3 mg, 4.5 mg, 6 mg
- Exelon patches: 4.6 mg/24 hours, 9.5 mg/24 hours, 13.3 mg/24 hours
- Generic rivastigmine patches: 4.6 mg/24 hours, 9.5 mg/24 hours, 13.3 mg/24 hours

VII. References

1. Exelon Patch Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/022083s028lbl.pdf. Accessed November 13, 2024.
2. Exelon. Prescribing Information. East Windsor, NJ: Aurobindo Pharma USA; June 2024. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c246a0e5-1e77-41ee-a7b3-384f21f2f2e0. Accessed November 13, 2024.
3. Qaseem A, Snow V, Cross JT, 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.
4. Grossberg GT, Tong G, Burke AD, Tariot PD. Present algorithms and future treatmens for Alzheimer's disease. J Alzheimers Dis. 2019;67(4):1157-1171.

5. Winslow BT, Onysko MK, Stob CM, and Hazlewood KA. Treatment of Alzheimer's disease. *Am Family Phys.* 2011;83(12):1403-1412.
6. 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.
7. Seppi K, Chaudhuri R, Coelho M, et al and the collaborators of the Parkinson's Disease Update on Non-Motor Symptoms Study Group on behalf of the Movement Disorders Society Evidence-Based Medicine Committee. Update on treatments for nonmotor symptoms of Parkinson's disease-an evidence-based medicine review. Mov Disord. 2019 Feb;34(2):180-198. doi: 10.1002/mds.27602.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; updated dosage and administration to include oral solution; references reviewed and updated.	10.21.20	02.21
1Q 2022 annual review: no significant changes; updated Section V Dosage and Administration and Section VI Product Availability; references reviewed and updated.	09.16.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
1Q 2023 annual review: no significant changes; added must use generic language for Exelon patch; references reviewed and updated.	11.14.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.19.23	02.24
1Q 2025 annual review: no significant changes; revised policy/criteria section to also include brand Exelon; references reviewed and updated.	11.13.24	02.25

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.