Clinical Policy: Rivastigmine (Exelon)

Reference Number: CP.PMN.101
Effective Date: 03.01.17
Last Review Date: 02.20
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 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 or galantamine 24 mg per day, unless contraindicated or clinically significant adverse effects are experienced;
   b. If member cannot take donepezil and galantamine 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:
Medicaid – 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
Medicaid – 12 months

C. 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): CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met 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:
Medicaid – 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 12 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): 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
galantamine (Razadyne®; Razadyne® ER)	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 once daily Capsule: 1.5 to 6 mg twice daily	Patch: 13.3 mg/24 hours transdermally Capsule: 12 mg/day
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; December 2018. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exelonpatch.pdf. Accessed October 30, 2019.
2. Exelon. Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exelon.pdf. Accessed October 30, 2019.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://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
New policy created.	11.16	02.17
1Q18 annual review: - No significant changes - Policy number changes from CP.PPA.22 to CP.PMN.XX - Age added per safety guidance endorsed by Centene Medical Affairs - Referenced reviewed and updated	11.14.17	02.18
1Q 2019 annual review: addition of HIM line of business; no significant changes; references reviewed and updated.	11.13.18	02.19
1Q 2020 annual review: no significant changes; removed HIM line of business; references reviewed and updated.	10.30.19	02.20

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.