

**Clinical Policy: Alzheimer’s Agents**  
 Reference Number: OH.PHAR.PPA.33  
 Effective Date: 01.01.2020  
 Last Review Date:  
 Line of Business: Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

**CNS AGENTS: ALZHEIMER’S AGENTS**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
DONEPEZIL 5mg, 10mg (generic of Aricept®) GALANTAMINE (generic of Razadyne™) GALANTAMINE 4mg/ml solution (generic of Razadyne™) GALANTAMINE ER (generic of Razadyne™ ER) MEMANTINE tablets (generic of Namenda®) RIVASTIGMINE capsules (generic of Exelon®)	DONEPEZIL ODT (generic of Aricept® ODT) DONEPEZIL 23mg (generic of Aricept® 23mg) MEMANTINE 10mg/5ml solution (generic of Namenda®) NAMENDA XR® (memantine ER) NAMZARIC® (memantine ER/donepezil) RIVASTIGMINE patch (generic of Exelon® patch)

**FDA Approved Indication(s)**

- Aricept ODT, Aricept 23mg, Razadyne, Namzaric, Exelon patch are indicated for mild to moderate Alzheimer’s disease.
- Aricept 23mg, Namenda, Namenda XR are indicated for moderate to severe Alzheimer’s disease
- Exelon patch is also indicated for severe Alzheimer’s dementia and mild to moderate dementia associated with Parkinson’s disease

**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 Aricept ODT, Aricept 23mg, Razadyne 4mg/ml, Namenda 10mg/5ml, Namenda XR, Namzaric, Exelon patch are **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

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

1. Diagnosis of Alzheimer's dementia;
2. Age  $\geq$  18 years;
3. Failure of a therapeutic trial of at least 30 days with at least two medications not requiring prior approval unless one of the following:
  - a. History of unacceptable or toxic side effects to medications not requiring prior approval
  - b. Contraindication to or drug-drug interaction with medications not requiring prior approval
  - c. Allergy to medications not requiring prior approval
  - d. If member is unable to swallow (Donepezil ODT, rivastigmine patch)

**Approval duration: 12 months**

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

1. Diagnosis of Parkinson's Disease Dementia;
2. Age  $\geq$  18 years;
3. Failure of  $\geq$  30 day trial of donepezil at doses up to 10 mg per day unless one of the following:
  - a. History of unacceptable or toxic side effects to medications not requiring prior approval
  - b. Contraindication to or drug-drug interaction with medications not requiring prior approval
  - c. Allergy to medications not requiring prior approval

**Approval duration: 12 months**

### II. 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.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents

### III. Appendices/General Information

## Clinical Policy: Alzheimer's Agents



### Appendix A: Abbreviation/Acronym Key

AD: Alzheimer's Dementia

FDA: Food and Drug Administration

PDD: Parkinson's Disease Dementia

### 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®; 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®)	AD (Namenda): 5 mg PO QD titrated up to 10 mg PO BID	AD (Namenda): 20 mg/day
rivastigmine (Exelon®) capsules	AD: 1.5mg BID titrated up to 6mg BID PDD: 1.5mg BID titrated up to 6mg BID	AD: 12mg/day PDD: 12mg/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

- Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

## IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

## V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

## VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	

**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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**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.

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