

## Clinical Policy: Galantamine (Razadyne, Razadyne ER)

Reference Number: CP.CPA.XX

Effective Date: 11.16.16

Last Review Date: 08.18

Line of Business: Commercial

[Revision Log](#)

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

### Description

Galantamine (Razadyne®, Razadyne® ER) is a cholinesterase inhibitor.

### FDA Approved Indication(s)

Razadyne and Razadyne ER are indicated for the treatment of mild to moderate dementia of the Alzheimer's type.

### 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 that Razadyne and Razadyne ER are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Dementia (must meet all):

1. Diagnosis of dementia;
2. Age  $\geq$  18 years;
3. Failure of donepezil or Exelon® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 24 mg/day.

##### Approval duration:

**Medicaid** – 12 months

**Commercial** – Length of Benefit

##### 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): CP.CPA.09 for commercial.

#### II. Continued Therapy

##### A. Mild to Moderate Dementia (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 24 mg/day.

##### Approval duration:

**Medicaid** – 12 months  
**Commercial** – Length of Benefit

**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.CPA.09 for commercial.

**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.CPA.09 for commercial or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

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®/Aricept ODT®)	Mild to moderate: 5 mg to 10 mg orally once daily	10 mg/day
	Moderate to severe: 10 to 23 mg orally once daily	23 mg/day
Exelon® (rivastigmine)	Oral: 1.5 mg orally twice daily initially. After a minimum of 2 weeks increase to 3 mg up to 6 mg twice daily if tolerated	Oral: 12 mg/day
	Transdermal: initiate with 4.6 mg patch daily; after a minimum of 4 weeks, increase to 9.5 mg or 13.3 mg once daily	Transdermal: 13.3 mg/24 hours

*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*

Not applicable

*Appendix D: General Information*

Not applicable

**V. Dosage and Administration**

Drug Name	Indication	Dosing Regimen	Maximum Dose
Galantamine (Razadyne)	Mild to moderate dementia of the Alzheimer's type	4 mg PO BID initially. Then titrate as tolerated with a minimum of 4 weeks between dose increases to 8 mg BID and 12 mg BID. Take with food.	12 mg BID
Galantamine (Razadyne ER)	Mild to moderate dementia of the Alzheimer's type	8 mg PO QAM initially. Then titrate as tolerated with a minimum of 4 weeks between dose increases to 16 mg daily and 24 mg daily. Take with food.	24 mg QD

**VI. Product Availability**

Drug Name	Availability
Razadyne®	Tablet: 4 mg, 8 mg, 12 mg Oral solution: 4 mg/mL
Razadyne ER®	Capsule: 8 mg, 16 mg, 24 mg

**VII. References**

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policy split from CP.CPA.102 into individual Razadyne policy; no significant changes; combined mild and moderate criteria sets; references reviewed and updated.	04.09.18	08.18

**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.

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