Clinical Policy: Galantamine (Razadyne, Razadyne ER)

Reference Number: CP.CPA.135
Effective Date: 11.16.16
Last Review Date: 08.19
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 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 ≥ 18 years;
3. Failure of donepezil or rivastigmine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 24 mg per day.

Approval duration: 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. 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 per day.

Approval duration: 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 Alzheimer's disease: 5 mg to 10 mg PO QD Moderate to severe Alzheimer's disease: 10 to 23 mg PO QD	10 mg/day 23 mg/day
Rivastigmine (Exelon®)	Oral: 1.5 mg PO BID initially. After a minimum of 2 weeks increase to 3 mg up to 6 mg BID if tolerated Transdermal: initiate with 4.6 mg patch topically daily; after a minimum of 4 weeks, increase to 9.5 mg or 13.3 mg once daily	Oral: 12 mg/day 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/Boxed Warnings

- Contraindication(s): Known hypersensitivity to galantamine hydrobromide or any excipients
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Galantamine (Razadyne)	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.	24 mg/day
Galantamine (Razadyne ER)	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.	24 mg/day

VI. Product Availability

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

VII. References

1. Razadyne/Razadyne ER® Prescribing Information. Titusville, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc; May 2018. Available at: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/RAZADYNE+ER-pi.pdf. Accessed May 21, 2019.
2. Aricept® Prescribing Information. Woodcliff Lake, NJ: Eisai Inc; December 2018. Available at: http://www.aricept.com/. Accessed May 21, 2019.
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6. Tariot PN, Farlow MR, Grossberg GT, et al. for the Memantine Study Group. Memantine treatment in patients with moderate to severe Alzheimer Disease already receiving donepezil; a randomized controlled trial. JAMA 2004;291(3):317-324.
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12. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 21, 2019.
13. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/.

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
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19

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

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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.

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