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

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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>donepezil (Aricept®/Aricept ODT®)</td>
<td>Mild to moderate Alzheimer’s disease: 5 mg to 10 mg PO QD</td>
<td>10 mg/day</td>
</tr>
<tr>
<td></td>
<td>Moderate to severe Alzheimer’s disease: 10 to 23 mg PO QD</td>
<td>23 mg/day</td>
</tr>
<tr>
<td>Rivastigmine (Exelon®)</td>
<td>Oral: 1.5 mg PO BID initially. After a minimum of 2 weeks increase to 3 mg up to 6 mg BID if tolerated</td>
<td>Oral: 12 mg/day</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>Transdermal: 13.3 mg/24 hours</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galantamine (Razadyne)</td>
<td>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.</td>
<td>24 mg/day</td>
</tr>
<tr>
<td>Galantamine (Razadyne ER)</td>
<td>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.</td>
<td>24 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galantamine (Razadyne)</td>
<td>Tablet: 4 mg, 8 mg, 12 mg Oral solution: 4 mg/mL</td>
</tr>
<tr>
<td>Galantamine (Razadyne ER)</td>
<td>Capsule: 8 mg, 16 mg, 24 mg</td>
</tr>
</tbody>
</table>

VII. References


### Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.09.18</td>
<td>08.18</td>
</tr>
<tr>
<td>05.21.19</td>
<td>08.19</td>
</tr>
</tbody>
</table>

#### 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.

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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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