



## STEP THERAPY POLICY

- POLICY:** Alzheimer's Disease Step Therapy Policy
- Adlarity<sup>®</sup> (donepezil transdermal system – Corium)
  - Aricept<sup>®</sup>, Aricept<sup>®</sup> ODT (donepezil tablets and orally disintegrating tablets – Pfizer/Eisai, generic)
  - Exelon<sup>®</sup> (rivastigmine capsules – Novartis, generic)
  - Exelon<sup>®</sup> Patch (rivastigmine transdermal system – Novartis, generic)
  - Namzaric<sup>™</sup> (memantine extended-release and donepezil capsules – Forest)
  - Razadyne<sup>®</sup> (galantamine tablets and oral solution – Janssen, generic)
  - Razadyne<sup>®</sup> ER (galantamine extended-release capsules – Janssen, generic)

**REVIEW DATE:** 12/01/2021; selected revision 07/20/2022

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### OVERVIEW

The acetylcholinesterase inhibitors (ChIs) [donepezil, rivastigmine, galantamine] and the *N*-methyl-D-aspartate (NMDA) antagonist memantine are indicated for the **treatment of Alzheimer's disease (AD)**.<sup>1-6</sup>

- Adlarity, donepezil, and rivastigmine transdermal are the only agents approved for **all degrees of AD [mild, moderate, and severe]**.
- Galantamine/galantamine extended-release (ER) and oral rivastigmine are approved for **mild to moderate AD**.
- Oral and transdermal rivastigmine are also indicated for the **treatment of mild to moderate dementia associated with Parkinson's disease (PD)**.
- Namzaric is indicated for the **treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on donepezil 10 mg once daily**.<sup>7</sup>

Namzaric is a fixed-dose combination containing donepezil and memantine ER.<sup>7</sup> This policy does not include the single-agent NMDA antagonists.

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 (A or B) Product prior to the use of a Step 2 (A or B) Product. If the Step Therapy rule is not met for the Step 2 (A or B) Product at the point of service, coverage will be determined by the Step Therapy criteria below. This program has two separate components: one for **generic acetylcholinesterase inhibitor products** (does NOT include donepezil 23 mg tablets) and one for the **Aricept 23 mg strength products (brand or generic)**. All approvals are provided for 1 year in duration.

**Automation:** A patient with a history of one Step 1 (A or B) Product within the 130-day look-back period is excluded from Step Therapy.

### Generic acetylcholinesterase inhibitor:

**Step 1A:** generic galantamine tablets or oral solution, generic galantamine extended-release capsules, generic rivastigmine capsules, generic donepezil tablets and orally disintegrating tablets (does NOT include donepezil 23 mg tablets), generic rivastigmine transdermal system

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**Step 2A:** Adlarity, Aricept 5 and 10 mg tablets, Aricept ODT, Exelon, Exelon Patch, Namzaric, Razadyne, Razadyne ER

**Aricept 23 mg strength (brand or generic):**

**Step 1B:** Aricept 10 mg tablets (brand or generic), Aricept ODT 10 mg (brand or generic)

**Step 2B:** Aricept 23 mg tablets (brand or generic)

**CRITERIA**

**Generic acetylcholinesterase inhibitor criteria**

1. If the patient has tried one Step 1A Product, approve a Step 2A Product.
2. No other exceptions are recommended.

**Aricept 23 mg strength (brand or generic) criteria**

1. If the patient has tried one Step 1B Product, approve a Step 2B Product.
2. No other exceptions are recommended.

**REFERENCES**

1. Aricept® tablets/Aricept® ODT (orally disintegrating tablets) [prescribing information]. Woodcliff Lake, NJ: Eisai; December 2018.
2. Razadyne® tablets and Razadyne™ ER extended-release capsules [prescribing information]. Titusville, NJ: Janssen; August 2021.
3. Exelon® capsules [prescribing information]. East Hanover, NJ: Novartis; December 2018.
4. Exelon® patch [prescribing information]. East Hanover, NJ: Novartis; December 2018.
5. Namenda® tablets and oral solution [prescribing information]. Madison, NJ: Allergan; November 2018.
6. Namenda XR® extended-release capsules [prescribing information]. Madison, NJ: Allergan; November 2019.
7. Namzaric™ capsules [prescribing information]. Cincinnati, OH: Forest; July 2016.
8. Adlarity® transdermal system [prescribing information]. Grand Rapids, MI: Corium; March 2022.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/11/2020
Annual Revision	No criteria changes.	12/01/2021
Selected Revision	<b>Adlarity:</b> Adlarity was added to the policy as a Step 2A product. No criteria changes.	07/20/2022