

STEP THERAPY POLICY

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

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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)**.¹⁻⁹

- Adlarity, donepezil, and transdermal rivastigmine 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)**.
- Memantine/donepezil ER capsules are indicated for the **treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on donepezil 10 mg once daily**.

Memantine ER/donepezil capsules are a fixed-dose combination containing donepezil and memantine ER.⁸

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. All approvals are provided for 1 year in duration.

Note: 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)**. This policy does not include the single-agent NMDA antagonists.

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

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

Step 2A: Adlarity, Aricept 5 and 10 mg tablets, Aricept ODT, Exelon, Exelon Patch, Namzaric (brand or generic), 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 [prescribing information]. Titusville, NJ: Janssen; August 2021.
3. Razadyne[®] ER extended-release capsules [prescribing information]. Titusville, NJ: Janssen; September 2022.
4. Exelon[®] capsules [prescribing information]. East Hanover, NJ: Novartis; December 2018.
5. Exelon[®] patch [prescribing information]. East Hanover, NJ: Novartis; May 2024.
6. Namenda[®] tablets and oral solution [prescribing information]. Madison, NJ: Allergan; November 2018.
7. Namenda XR[®] extended-release capsules [prescribing information]. Madison, NJ: Allergan; November 2019.
8. Namzaric[®] extended-release capsules [prescribing information]. Madison, NJ: Allergan; July 2019.
9. Adlarity[®] transdermal system [prescribing information]. Grand Rapids, MI: Corium; March 2022.