

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 extended-release and donepezil capsules – Forest)
 - Razadyne[®] (galantamine tablets and oral solution – Janssen, generic)
 - Razadyne[®] ER (galantamine extended-release capsules – Janssen, generic)

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

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)**.¹⁻⁶

- 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**.⁷

Namzaric is a fixed-dose combination containing donepezil and memantine ER.⁷ 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

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	Adlarity: Adlarity was added to the policy as a Step 2A product. No criteria changes.	07/20/2022