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: 12/06/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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).[1-7]

- 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)**.

- 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**.

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

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.

Alzheimer's Disease product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

Generic acetylcholinesterase inhibitor:

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, 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.

Aricept 23 mg strength (brand or generic) criteria

1. If the patient has tried one Step 1B Product, approve a Step 2B Product.

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]. Madison, NJ: Allergan; January 2019.
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.	12/07/2022
Annual Revision	No criteria changes.	12/06/2023

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