SmartPA Criteria Proposal

Drug/Drug Class:	Alzheimer's Agents, Acetylcholinesterase Inhibitors, N-Methyl-D-Aspartate Receptor Antagonists & Combinations PDL Edit
First Implementation Date:	May 21, 2008
Proposed Date:	December 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state specific preferred drug list.

Why Issue Selected: Alzheimer's Disease (AD) is the most common cause of dementia, accounting for 60 to 70 percent of dementia disorders in the elderly. AD is characterized by progressive cognitive decline associated with impairment of activities of daily living and behavioral disturbances. Patients with AD eventually lose all cognitive, analytical, and physical functioning. Although the causes of AD have not been completely identified, the etiology of the disease is thought to be multifactorial. The discovery of vast cholinergic cell loss has led to the cholinergic hypothesis and the development of drugs that target the cholinergic system. The cholinergic hypothesis suggests that a dysfunction of acetylcholine (ACh)-containing neurons in the brain plays a large role in the decline of cognitive function seen in patients with AD. The degree of cognitive impairment is related to the amount of cholinergic loss and the density of extracellular amyloid plaques. These plaques significantly interfere with neuronal transmission.

Acetylcholinesterase inhibitors (AChEIs) exert their therapeutic effect by enhancing cholinergic function by increasing the concentration of ACh through reversible inhibition of its hydrolysis by AChE. The resulting ACh improves cognition. Glutamate, the primary excitatory amino acid in the central nervous system, may contribute to the pathogenesis of AD by overstimulating various glutamate receptors leading to excitotoxicity and neuronal cell death. N-methyl-D-aspartate (NMDA) receptor antagonists, such as memantine, are uncompetitive antagonists of the NMDA type of glutamate receptors.

Aduhelm™ (aducanumab-avwa), an intravenously administered amyloid beta-directed antibody, will not be reviewed within this PDL edit. Criteria for Aduhelm approval can be found within the Aduhelm Clinical Edit.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Donepezil ODT • Donepezil 5, 10 mg Tabs • Exelon® Patch • Memantine Tabs	• Adlarity® • Aricept® • Donepezil 23 mg Tabs • Galantamine Soln/Tabs • Galantamine ER • Memantine Soln • Memantine ER • Namenda® • Namenda XR® • Namzaric® • Razadyne® • Razadyne ER® • Rivastigmine

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Alzheimer's Agents, Acetylcholinesterase Inhibitors, N-Methyl-D-Aspartate Receptor Antagonists & Combinations
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **OR**
- For Namzaric: Documented compliance on memantine and donepezil single agents (90/120 days)

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- For donepezil: claim is dosed above 1 tablet per day

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☒

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: CENTRAL NERVOUS SYSTEM: Alzheimer’s Agents, Acetylcholinesterase Inhibitors, N-Methyl-D-Aspartate Receptor Antagonists and Combinations”, Gainwell Technologies; Last updated October 19, 2022.
- Evidence-Based Medicine Analysis: “Alzheimer's Agents”, UMKC-DIC; August 2022.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-line; 2022.