

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



Policy:	Alzheimer's	P&T Date:	5/11/2021
Therapeutic Class:	Neurologic Disorders	Review History:	5/20, 5/19, 5/18, 2/17, 2/16,
LOB Affected:	MCL	(month/year)	11/12, 9/12, 5/11

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Alzheimer's disease is the most common form of dementia that currently has no cure. Progressive memory loss and cognitive decline are key characteristics of Alzheimer's.¹ The role that medications have in Alzheimer's treatment is to assist in reducing worsening cognitive symptoms (e.g. memory loss, confusion, problems with thinking and reasoning) as the disease itself continues to manifest. This review will examine the currently available agents for Alzheimer's disease and their coverage criteria.

Table 1: Available Alzheimer's Treatment Agents (Current as of 2/2021)

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Avg Cost/month	Notes/Restriction	
Acetylcholinesterase Inhibitors	Donepezil (Aricept)	Tablets:				
		5 mg	F	\$1.92		
		10 mg	F	\$1.82		
		23 mg	NF	--		
		ODT:				
		5 mg	NF	--		
			10 mg	NF	--	
	Rivastigmine Tartrate (Exelon)	Capsule:				Reserved for mild-to-moderate dementia of the Alzheimer's type with MMSE score between 10 and 26
		1.5 mg	PA	--		
		3 mg	PA	\$20.43		
		4.5 mg	PA	--		
		6 mg	PA	--		
		Solution:				
		2 mg/ml	NF	--	--	
		24 hr Patch :				
4.6 mg		NF	--			
9.5 mg	NF	--				
13.3 mg	NF	--				
Galantamine Hydrobromide (Razadyne, Razadyne ER)	ER Capsule:					
	8 mg	NF	--			
	16 mg	NF				
	24 mg	NF				
	Solution:					
	4 mg/mL	NF	--			
	Tablet:					
4 mg	NF	--				
8 mg	NF	--				

		12 mg	NF	--		
N-Methyl-D-Aspartate (NMDA) Receptor Inhibitor	Memantine (Namenda, Namenda XR)	Tablet:				Reserved for moderate to severe dementia of Alzheimer's type MMSE score of 3-14
		5 mg	PA	\$5.06		
		10 mg	PA	\$5.38		
		Solution:				
		2 mg/mL	PA	--		
		XR Capsule:				
		7 mg	NF	--		
		14mg	NF	--		
		21 mg	NF	--		
		28 mg	NF	--		
		Namenda Titration Pak	PA	\$16.29	Reserved for moderate to severe dementia of Alzheimer's type MMSE score of 3-14	
Namenda XR Titration Pak	NF	--				
Combination Agent	Memantine XR/Donepezil (Namzaric)	Capsule:				
		7-10 mg	NF	--		
		14-10 mg	NF	--		
		21-10 mg	NF	--		
		28-10 mg	NF	--		
		Titration Pack	NF	--		

ODT = Orally Disintegrating Tablet, ER/XR = Extended Release, F = Formulary, NF = Non-Formulary, ST = Step therapy, PA = Prior Authorization required, MMSE = mini-mental state examination.

Clinical Justification:

Pharmacologic therapy for Alzheimer's is recommended to begin with an acetylcholinesterase inhibitor, followed by an NMDA receptor inhibitor.² Combination therapy of both classes can be considered in moderate to severe Alzheimer's disease.³ Donepezil is the most commonly used acetylcholinesterase inhibitor with the common dosage being 10 mg daily. Donepezil 23 mg has been shown to have significantly more intolerable side effects without as much difference in clinical benefit compared to Donepezil 10 mg.

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Acetylcholinesterase Inhibitors
<i>Donepezil (Aricept), Rivastigmine Tartrate capsules (Exelon), Galantamine Hydrobromide (Razadyne, Razadyne ER)</i>

Donepezil (Aricept), Rivastigmine Tartrate capsules (Exelon)

- Coverage Criteria:**
 - Donepezil: None
 - Rivastigmine: It is reserved for patients with mild-to-moderate dementia of the Alzheimer's type with MMSE score between 10 and 26.
- Limits:** None
- Required Information for Approval:**
 - Rivastigmine:
 - Documentation of mild-to-moderate dementia of the Alzheimer's type
 - MMSE score between 10 to 26
- Non-Formulary:** Rivastigmine Tartrate patches and solutions , Galantamine Hydrobromide

N-Methyl-D-Aspartate (NMDA) Receptor Antagonists
<i>Memantine (Namenda, Namenda XR)</i>

Memantine (Namenda, Namenda XR)

- Coverage Criteria:** Reserved for patients with moderate-to-severe dementia of Alzheimer's type, based on MMSE score of 3-14.
- Limits:** None
- Required Information for Approval:**
 - Documentation of moderate-to-severe dementia of Alzheimer's type
 - MMSE score between 3 to 14

Combination Agents
<i>Namzaric (Donepezil/Namenda XR)</i>

- Non-Formulary:** Namzaric (Donepezil/Namenda XR)

REFERENCES

1. Winslow BT, Onysko MK, Stob CM, and Hazlewood KA. Treatment of Alzheimer Disease. *Am Fam Physician*. 2011;83(12):1403-1412.
2. Qaseem A, Snow V, Cross JT, et. al. Current Pharmacologic Treatment of Dementia: A Clinical Practice Guidelines from the American College of Physicians and the American Academy of Family Physicians. *Ann Intern Med*. 2008;148(5):370-378.
3. American Psychiatric Association. *Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias*. 2nd ed. Arlington, Va.: American Psychiatric Association; 2007.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Aricept 23 5-17-11.docx	5/2011	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment PT 9-28-12.xlsx	9/2012	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment for PT 11-20-12.xlsx	11/2012	Allen Shek PharmD BCPS
Update to Policy	HPSJ Coverage Policy – Neurologic Disorders – Alzheimer’s 2016-02.docx	2/2016	Johnathan Yeh, PharmD

Update to Policy	HPSJ Coverage Policy – Neurologic Disorders – Alzheimer’s 2017-02.docx	2/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Neurologic Disorders – Alzheimer’s 2018-05.docx	5/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Neurologic Disorders – Alzheimer’s 2019-05.docx	5/2019	Matthew Garrett, PharmD
Review of Policy	HPSJ Coverage Policy – Neurologic Disorders – Alzheimer’s.docx	5/2020	Matthew Garrett, PharmD
Review of Policy	Alzheimer’s	5/2021	Matthew Garrett, PharmD