PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

NAMENDA
(memantine hydrochloride)

Prior Authorization applies only to patients less than 30 years of age.

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Age Edit ***Ref # 511-B***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS
Namenda and Namenda XR are indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

Compendial Uses
Vascular Dementia[3, 7, 8]

COVERAGE CRITERIA
The requested drug will be covered with prior authorization for patients less than 30 years of age when the following criteria are met:

- The patient has any of the following diagnoses: A) moderate to severe dementia of the Alzheimer's type, B) vascular dementia

AND

- If the request is for continuation of therapy, the medication continues to provide benefit to the patient
  [Note: If slowing decline of cognitive function is no longer a goal, or if the patient is rapidly declining, treatment with the medication is no longer appropriate.]
  OR
- The diagnosis is supported by a validated cognitive assessment within the past 12 months

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. These criteria only apply to patients less than 30 years of age. Namenda (memantine) and Namenda XR (memantine extended-release) are indicated for the treatment of moderate to severe dementia of the Alzheimer's type.[1,2] Namenda may also be effective in improving cognitive function in patients with vascular dementia.[3, 7, 8]

The American College of Medical Genetics (ACMG) practice guidelines regarding genetic counseling and testing for Alzheimer disease (AD) provide clinicians with a framework for assessing their patients' genetic risk for AD, identifying which individuals may benefit from genetic testing, and providing the key elements of genetic counseling for AD. Alzheimer disease currently affects more than 5 million Americans and although the majority of cases occur in the elderly, approximately 250,000 people have early-onset AD (EOAD) with onset of symptoms before age 65 years. Per these guidelines, there are known deterministic (causative) genes in which mutations are associated with early-onset Alzheimer disease in patients as young as 30 years of age.[9]

Prior to initiating or renewing Namenda therapy, patients should undergo a comprehensive cognitive assessment. The comprehensive cognitive assessment should include evaluation with a validated cognitive assessment test that utilizes a

standardized scale. Tests commonly used in clinical practice for Alzheimer's dementia are the Mini-Mental State Exam (MMSE-adjusted for age/education), the Alzheimer's Disease Assessment Scale, Cognitive Subsection (ADAS-Cog), or the Blessed Information-Memory Concentration Test (BIMC). This assessment should have been completed within the previous 6 months for patients new to Namenda therapy and at least annually for patients who are continuing therapy, to allow clinicians to evaluate whether the drug continues to provide benefit to the patient.[1-6]

There is no evidence that Namenda prevents or slows neurodegeneration in patients with Alzheimer's disease. If slowing decline of cognitive function is no longer a goal, or if the patient is rapidly declining, treatment with Namenda is no longer appropriate.[1-6]

REFERENCES

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5. Rabins P, Blacker D, Rovner B. Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias, Second Edition. *Am J Psychiatry*. 2007; 164(12S):1-56.
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8. Wilcock G, Mobius H, Stoffier A. A double blind, placebo controlled multicenter study of memantine in mild to moderate vascular dementia. *Int Clin Psychopharmacol.* 2002; 17:297-305.
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CRITERIA FOR APPROVAL

1	Does the patient have any of the following diagnoses: A) moderate to severe dementia of the Alzheimer's type, B) vascular dementia? [If no, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If no, then skip to question 4.]	Yes	No
3	Does the medication continue to provide benefit to the patient? [Note: If slowing decline of cognitive function is no longer a goal, or if the patient is rapidly declining, treatment with the medication is no longer appropriate.] [No further questions.]	Yes	No

4	Is the diagnosis supported by a validated cognitive assessment within the past 12 months?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: - Moderate to severe dementia of the Alzheimer's type - Vascular dementia Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Go to 4	
3.	Approve, 12 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when it continues to provide benefit to you. Your request has been denied based on the information we have. [Short Description: No continued benefit]
4.	Approve, 12 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had an assessment in the past 12 months that supports your condition. Your request has been denied based on the information we have. [Short Description: No recent assessment]