PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

NAMENDA (all dosage forms)
(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.

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 a diagnosis of moderate to severe dementia of the Alzheimer's type

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.

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.[5]

REFERENCES

1. Namenda [package insert]. Madison, NJ: Allergan USA, Inc.; November 2018.
2. Namenda XR [package insert]. Irvine, CA: Allergan USA, Inc.; October 2016.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed May 2019.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed May 2019.
5. Goldman JS, Hahn SE, Catania JW, et. al. ACMG Practice Guidelines. Genetic counseling and testing for Alzheimer disease: Joint practice guidelines of the American College of Medical Genetics and the National Society of Genetic Counselors. *Genetics in Medicine* June 2011; 13:597-605.

Written by: UM Development (JG)
Date Written: 10/2003
Revised: (NB) 10/2004; (JG) 10/2005; (NB) 06/2006, 07/2006; (AM) 09/2007 (converted to new non-MDC version), 05/2008, 05/2009 (TM) 05/2010; (RP) 07/2011, 06/2012, 06/2013, (SE) 02/2014; (SE/RP) 06/2014, (SE) 10/2014 (CMS requested changes); (RP) 05/2015; (JH) 05/2016 (no clinical changes), (SE) 06/2016 (created separate Med D); (RP) 05/2017, 05/2018 (no clinical changes); (DFW) 05/2019 (no clinical changes/removed MDC designation from title/document)
Reviewed: CRC: 10/2003; CDPR/Medical Affairs (MM): 10/2004, 10/2005, 06/2006, 07/2006; (WF): 09/2007, 05/2008, 05/2009, 05/2010; (KP) 07/2011, 06/2012; (SS) 06/2013, (KP) 02/2014; (LMS) 06/2014; (DNC) 05/2015; (ABM) 05/2017
External Review: 12/2003, 12/2004, 02/2006, 12/2006, 02/2008, 08/2008, 10/2009, 09/2010, 10/2011, 10/2012, 10/2013, 03/2014, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 10/2019

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of moderate to severe dementia of the Alzheimer's type?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1	
Yes to question(s)	**No to question(s)**

1	None

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have moderate to severe dementia of the Alzheimer's type. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]