STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Namenda (memantine) for Autism Spectrum Disorder
MED-004

Iowa Medicaid Program:	Exception to Policy	**Effective Date:**	01/18/2013
Revision Number:	13	**Last Rev Date:**	07/21/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/19/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	08/23/2019

Overview

Medication: [1]	memantine
Brand Name:	Namenda®
Pharmacologic Category:	N-Methyl-D-Aspartate (NMDA) Receptor Antagonist
FDA-Approved Indication(s):	Treatment of moderate to severe dementia of the Alzheimer's type

How Supplied:	• Immediate-release tablet for oral administration, 5 mg and 10 mg
	• Additional dosage forms which are NOT covered under this policy include:
	  ○ Capsule, extended-release 24-hour: 7 mg, 14 mg, 21 mg, 28 mg
	  ○ Oral solution: 2 mg/mL

Dosage and Administration:	Starting dose is 5 mg/day, increasing in 5 mg increments (minimum recommended interval between dose increases is 1 week) to final dose of 10 mg twice daily.
Benefit Category:	Medical

Descriptive Narrative

Memantine is an N-methyl-D-aspartic acid receptor antagonist, approved by the FDA for treatment of moderate to severe Alzheimer's dementia in adults. It is an investigational treatment for children with autism spectrum disorders (ASDs). Several small, open-label studies and case series have supported its use for symptoms of hyperactivity, lethargy, irritability, language function and social behavior in at least a subset of this population, with strongest effects in verbal language function. There are currently no published randomized, placebo-controlled, blinded clinical trials published. No major medical societies have guidelines recommending its use.

Memantine is not covered under regular Medicaid for indications related to autism. It can only be considered under Early and Periodic Screening, Diagnosis and Treatment program as an Exception to Policy (ETP).

Criteria

1. Children up to 21 years of age with autism spectrum disorder (ASD) may be considered for memantine if **ALL** of the following are met:
   A. Documentation is provided of at least **ONE** of the following behavioral abnormalities causing measurable problems in educational progress, home life or medical treatment:
      1) Lethargy; **OR**
      2) Irritability; **OR**
      3) Deficits in expressive or receptive language function; **OR**
      4) Social withdrawal; **OR**
      5) Self-stimulatory stereotypic behaviors; **AND**
   B. Documentation is provided of at least **TWO** of the following have been used appropriately* for at least 6 months:
      1) Risperidone; **OR**
      2) At least one selective serotonin reuptake inhibitor; **OR**
      3) At least one stimulant medication; **OR**
      4) Aripiprazole or quetiapine; **AND**
   C. Therapeutic effects of the above medications, at optimal doses have been inadequate or adverse reactions have occurred which required discontinuing the medication; **AND**
   D. Ongoing intensive behavioral interventions have shown inadequate response; **AND**
   E. A care plan is submitted for the member, including medication, behavioral and educational goals, and plan; **AND**
   F. The medication is prescribed by a psychiatrist, psychiatric nurse practitioner, psychiatric physician assistant, or developmental pediatric provider; **AND**

2. Initial ETPs meeting the above criteria can be approved for a 6-month trial. For continued approval after that time, **ALL** of the following must be met:
   A. Clinically significant adverse effects of the medication have not been observed; **AND**
   B. Compliance with the medication has been recorded; **AND**
   C. The member has demonstrated significant clinical improvement of signs and symptoms as documented by **ALL** of the following:
      1) Substantial improvement in target behaviors on subjective and/or objective reports from family, educational staff or clinical staff involved in the member's daily care; **AND**
      2) Sustained improvement in scores on a standardized, validated psychometric, behavioral, or educational evaluation tool; **AND**
      3) The clinical improvement has been validated by a licensed healthcare professional (other than the prescribing physician), and a member of the interdisciplinary team (other than the parent).

* *"Used appropriately"* means that the medication is used for an indication for which it is known to have an impact and that dose has been appropriately titrated, according to dosing recommendations of the manufacturer, or best available evidence. Providing a dosing reference is the responsibility of the provider when doses not approved by the manufacturer are used.

Members who are older than 21 years of age will not be approved through QIO Services.

Memantine is considered investigational and will not be covered for the following:

1. Autism spectrum disorder (ASD) not meeting the above criteria.
2. Down syndrome not associated with Alzheimer-type dementia.
3. Attention-deficit hyperactivity disorder.
4. Obsessive-compulsive disorder.
5. Oppositional-defiant disorder.
6. Depression.
7. Intellectual disabilities not associated with ASD.
8. Developmental disorders not associated with ASD.
9. Parkinson's disease.
10. Chemical dependency/alcoholism.
11. Pain syndromes.
12. Glaucoma.
13. Hypertension.
14. AIDS dementia.
15. Nystagmus.
16. Migraines.

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

NDC	Description
72606-0614	Memantine hydrochloride tablets, 5 mg
72578-0004	Memantine hydrochloride tablets, 10 mg
72606-0515	Memantine hydrochloride tablets, 10 mg

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

This criteria was developed with input from a panel of 6 Iowa clinical psychiatrists. The pharmacy DUR mental health advisory group, which had some overlap in membership, was also invited to comment (Spring/Summer of 2012).

[1] Memantine drug information. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed July 10, 2023.

Safety Study of Memantine in Pediatric Patients With Autism, Asperger's Disorder or Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). ClinicalTrials.gov identifier: NCT01592773. Updated February 16, 2015. www.clinicaltrials.gov/study/NCT01592773. Accessed July 12, 2023.

Doyle CA and McDougle CJ, Pharmacotherapy to control behavioral symptoms in children with autism. *Expert Opin. Pharmacother.* (2012) 13(11) 1615-1629.

A Systematic Review of Medical Treatments for Children With Autism Spectrum Disorders, McPheeters, et al. Pediatrics, Vol 127, No. 5, May 1, 2011.

Comparative Effectiveness of Therapies for Children with Autism Spectrum Disorders: Clinician Guide. Agency for Healthcare Research and Quality, June 2011, 2 pp. Discusses the available evidence on the effectiveness, benefits, and harms of therapies used to address the core and associated symptoms seen among children aged 2-12 years with autism spectrum disorders. (AHRQ 11-EHC029-3).

American Psychiatric Association. Diagnostic and Statistical Manual, 5th Ed. (DSM-V).

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
	CAC		

Signature

Change Date	Changed By	Description of Change	Version
	CAC		

Signature

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review.	13

Signature

William (Bill) Jagiello, DO

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
7/15/2022	CAC	Formatting changes. Updated drug information reference.	12
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
7/16/2021	CAC	Updated references. Updated NDC codes. Added Overview section. Added Compliance section. Formatting changes.	11
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/16/2020	CAC	Revised ASD name and title. Minor formatting changes.	10
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
8/17/2018	CAC	Added to Criteria #1, F – "or developmental pediatric provider".	9
Signature			
C. David Smith, MD		William (Bill) Jagiello, DO	

Change Date	Changed By	Description of Change	Version
7/15/2016	Medical Director	Under Criteria, added information on controlled trial in children with autism.	8
Signature			

Change Date	Changed By	Description of Change	Version
7/17/2015	CAC	Added last paragraph in References.	7
Signature			

Change Date	Changed By	Description of Change	Version
7/14/2015	Medical Director	Criteria #1, #4a, and #4h removed reference to Pervasive Developmental disorder. Criterion #4g added "not associated with ASD". Under References removed individual names and listed as "panel" and added DSM-V reference.	6
Signature			

Change Date	Changed By	Description of Change	Version
7/18/2014	Medical Director	Formatting changes.	5
Signature			

Change Date	Changed By	Description of Change	Version
10/19/2012	Medical Director	Complete revision.	4
Signature			

Change Date	Changed By	Description of Change	Version
7/27/2012	CAC	Generic name of medication added.	3
Signature			

CAC = Medicaid Clinical Advisory Committee