Memantine (Namenda) for Autistic Spectrum Disorder (ASD) Criteria

<table>
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<tr>
<th>Iowa Medicaid Program:</th>
<th>Exception to Policy</th>
<th>Effective Date:</th>
<th>1/18/2013</th>
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<tr>
<td>Revision Number:</td>
<td>8</td>
<td>Last Review Date:</td>
<td>7/15/2016</td>
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<tr>
<td>Reviewed By:</td>
<td>Medicaid Clinical Advisory Committee</td>
<td>Next Review Date:</td>
<td>7/2017</td>
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<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>9/20/2016</td>
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Criteria:
Memantine is an N-Methyl-D-Aspartic Acid (NMDA) receptor antagonist, approved by the United States Food and Drug Administration (FDA) for treatment of moderate to severe Alzheimer’s Dementia in adults. It is an investigational treatment for children with autistic spectrum disorders. 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 (EPSDT) as an exception to policy (ETP).

1. Children up to 21 years of age with autistic 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:
      - Lethargy
      - Irritability
      - Deficits in expressive or receptive language function
      - Social withdrawal
      - Self-stimulatory stereotypic behaviors
   b. Documentation is provided of AT LEAST TWO of the following have been used appropriately* for at least six months:
      - Risperidone
      - At least one Selective Serotonin Reuptake Inhibitor (SSRI)
      - At least one stimulant medication
      - Aripiprazole or quetiapine

   *“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.

c. Therapeutic effects of the above medications, at optimal doses have been inadequate OR adverse reactions have occurred which required discontinuing the medication.

d. Ongoing intensive behavioral interventions have shown inadequate response.

e. A care plan is submitted for the member, including medication, behavioral and educational goals and plan.
f. The medication is prescribed by a psychiatrist, psychiatric nurse practitioner or psychiatric physician assistant.

2. Initial ETPs meeting the above criteria can be approved for a six 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.
   b. Compliance with the medication has been recorded.
   c. The member has demonstrated significant clinical improvement of signs and symptoms as documented by ALL of the following:
      • 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
      • Sustained improvement in scores on a standardized, validated psychometric, behavioral OR educational evaluation tool
      • The clinical improvement has been validated by a licensed health care professional (other than the prescribing physician), and a member of the interdisciplinary team (other than the parent).

3. Members who are over 21 years of age will not be approved through Medical Services.

4. Memantine is considered investigational and will not be covered for the following:
   a. Autistic spectrum disorder (ASD) not meeting the above criteria.
   b. Down syndrome not associated with Alzheimer-type dementia
   c. Attention-deficit hyperactivity disorder
   d. Obsessive-compulsive disorder
   e. Oppositional-defiant disorder
   f. Depression
   g. Intellectual disabilities not associated with ASD
   h. Developmental disorders not associated with ASD
   i. Parkinson’s Disease
   j. Chemical dependency/alcoholism
   k. Pain syndromes
   l. Glaucoma
   m. Hypertension
   n. AIDS dementia
   o. Nystagmus
   p. Migraines

NDC Code:
0456-3202-12

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

Clinicaltrials.gov/ct2/show/NCT01592773 Accessed 08-15-12

References Used (cont.):


Namenda prescribing information accessed from Namenda.com on 9-19-12


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.

Change History:

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<tr>
<th>Change Date:</th>
<th>Changed By:</th>
<th>Description of Change:</th>
<th>New Version Number:</th>
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<tr>
<td>7/27/12</td>
<td>CAC</td>
<td>generic name of medication</td>
<td>3</td>
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<td>10/19/12</td>
<td>Medical Director</td>
<td>Complete revision</td>
<td>4</td>
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<tr>
<td>7/18/14</td>
<td>Medical Director</td>
<td>Formatting changes</td>
<td>5</td>
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<td>7/14/15</td>
<td>Medical Director</td>
<td>Criteria #1, #4a, and #4h removed reference to Pervasive Developmental disorder (PDD). Criterion #4g added “not associated with ASD”. Under References Used, removed individual names and listed as “panel” and added DSM-V reference.</td>
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<td>7/17/15</td>
<td>CAC</td>
<td>Added last paragraph in References Used.</td>
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<td>Medical Director</td>
<td>Under Criteria, added information on controlled trial in children with autism</td>
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C. David Smith, MD