

Title: Alzheimer's Agents For Members Less Than 55 Years of Age

Origination: 01/31/06	Revised: 05/28/08	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Cholinesterase inhibitors reversibly inhibit the enzyme cholinesterase, thereby enhancing cholinergic function. Cholinesterase inhibitors are indicated for the treatment of mild to moderate dementia of the Alzheimer's type. Cholinesterase inhibitors include:
 - Aricept (donepezil)
 - Cognex (tacrine hydrochloride)
 - Razadyne (galantamine hydrobromide)
- NMDA receptor antagonists reduce the excitatory effects of the central nervous system and the symptoms of Alzheimer's disease. NMDA receptor antagonists are indicated for the treatment of moderate to severe dementia of the Alzheimer's type. NMDA receptor antagonists include, but are not limited to Namenda (memantine).

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Title: Alzheimer's Agents For Members Less Than 55 Years of Age

Procedure:

1.0 Request for *initial therapy* with Alzheimer's agents requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:

1.1 Requesting independent practitioner must be a neurologist or psychiatrist; **AND**

1.2 Diagnosis of Alzheimer's disease as evidenced by at least two (2) of the following:

1.2.1 Cognitive symptoms impairment:

1.2.1.1 Memory impairment (impaired ability to learn new information or to recall previously learned information);

1.2.1.2 Aphasia (language disturbance);

1.2.1.3 Apraxia (impaired ability to carry out motor activities despite intact motor function);

1.2.1.4 Agnosia (failure to recognize or identify objects despite intact sensory function);

1.2.1.5 Disturbance in executive functioning (i.e. planning, organizing, sequencing, abstracting);

1.2.2 Non-cognitive symptoms impairment:

1.2.2.1 Mood disturbances (i.e., depression, frustration);

1.2.2.2 Psychotic symptoms (i.e., hallucinations, delusions, suspiciousness);

1.2.2.3 Disruptive behaviors (i.e., agitation, aggression, hyperactivity, wandering, uncooperativeness);

AND

1.2.2 Results of Folstein Mini-Mental Status Exam (MMSE) or similar assessment receive a score of 10 to 28 (lower score signifies greater severity); **OR**

1.2.2 Perform a Memory Impairment Scale (MIS) and/or a '5 word' test;⁹

AND

Title: Alzheimer's Agents For Members Less Than 55 Years of Age

Procedure, continued:

- 1.0 Request for *initial therapy* with Alzheimer's agents requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following, continued:
 - 1.3 Exclusion of other possible causes of dementia include, but are not limited to:
 - 1.3.1 Cerebral vascular disease;
 - 1.3.2 Stroke;
 - 1.3.3 Alcoholism;
 - 1.3.4 Head trauma;
 - 1.3.5 Vitamin B12 deficiency;
 - 1.3.6 Pick's disease;
 - 1.3.7 Huntington's disease;
 - 1.3.8 Creutzfeldt-Jakob disease;
 - 1.3.9 Hypothyroidism;
 - 1.3.10 Medication use (anticholinergics, sedatives);
 - 1.4 If criteria are met, initial request may be approved for up to three (3) months.
- 2.0 Request for *continuation of therapy* beyond initial authorization period for Alzheimer's agents requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:
 - 2.1 Member demonstrates lack of intolerable or serious adverse effect; **AND**
 - 2.2 Reduction in Member's signs and symptoms; **OR**
 - 2.2 Completion of global assessments indicates improvement:⁶
 - 2.2.1 Clinician's Interview-Based Impression of Change-Plus Caregiver Input (CICIC-Plus);
 - 2.2.2 Clinician's Global Impression of Change;
 - 2.3 If criteria are met, approvable for a maximum of one (1) year of therapy.

Title: Alzheimer's Agents For Members Less Than 55 Years of Age

References:

1. Alzheimer's Disease. Alzheimer's Association. 2008. Accessed 04/14/08.
2. American Psychiatric Association (APA). Practice Guidelines For the Treatment of Patients With Alzheimer's Disease and Other Dementias. *Am. J. Psychiatry*. 2007:1-86.
3. *Aricept* (Donepezil hydrochloride) Full Prescribing Information. Pfizer, Inc. New York, NY. 2006.
4. Crismon, M. and Eggert, A. *Alzheimer's Disease*. In: Dippiro, J. et al. *Pharmacotherapy: A Pathophysiologic Approach*; 4th Edition. Appleton & Lange. Stamford, Connecticut. 1999:1065-1081.
5. Geldmacher DS. Treatment guidelines for Alzheimer's disease: redefining perceptions in primary care. *Prim Care Companion J Clin Psychiatry*. 2007;9(2):113-21.
6. Knopman, D. et al. Practice Parameter: Diagnosis of Dementia (An Evidence-Based Review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2001 (reviewed 2003);8(56):1143-1153.
7. *Namenda* (Memantine) Full Prescribing Information. Forest Pharmaceuticals. St. Louis, MO. 2007.
8. *Razadyne* (Galantamine hydrobromide) Full Prescribing Information. Ortho-McNeil Neurologics, Inc. Titusville, NJ. 2007.
9. Waldemar G, Dubois B, Emre M, Georges J, McKeith IG, Rossor M, Scheltens P, Tariska P, Winblad B; EFNS. Recommendations for the diagnosis and management of Alzheimer's disease and other disorders associated with dementia: EFNS guideline. *Eur J Neurol*. 2007 Jan;14(1):e1-26. Review.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee.

Disclaimer Information, continued:

Title: Alzheimer's Agents For Members Less Than 55 Years of Age

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.