Oscar Clinical Guideline: Memantine (Namenda) (PG213, Ver. 2)

Memantine (Namenda)

- Memantine Oral capsule, extended release
- Memantine Oral solution
- Memantine Oral tablet
- Memantine Hydrochloride 5mg & 10mg Tablet Titration Pak
- Namenda XR Titration Pak

Summary

Alzheimer's disease (AD) and Parkinson's disease (PD) are progressive neurodegenerative disorders that can lead to dementia. Alzheimer's dementia is characterized by cognitive decline, memory impairment, and functional disability, while Parkinson's disease dementia (PDD) typically presents with impairments in executive function, memory retrieval, and attention in the setting of an established PD diagnosis. Treatment goals for both types of dementia involve improving cognitive function and overall quality of life. Alzheimer's disease is the most common cause of dementia, affecting millions of people worldwide.

Alzheimer's dementia is often treated with acetylcholinesterase inhibitors (AChEIs), such as donepezil (Aricept), rivastigmine (Exelon), and galantamine (Razadyne), as first-line therapy for those with mild, moderate or severe dementia. Alternative therapies include N-methyl-D-aspartate (NMDA) receptor

antagonists such as memantine (Namenda) for moderate-to-severe dementia - which can be used as monotherapy or combined with AChEIs. Additionally, amyloid-targeting therapies, such as Leqembi (lecanemab) and Kisulna (donanemab), are indicated for initiation in those with mild cognitive impairment or mild dementia.

Memantine (Namenda) is an N-methyl-D-aspartate (NMDA) receptor antagonist used primarily for the treatment of moderate-to-severe Alzheimer's disease (AD).

- Memantine works by regulating glutamate activity, which is thought to play a role in the pathogenesis of AD. It has shown modest benefits in slowing cognitive decline and improving functional abilities in patients with moderate to severe AD. While not curative, memantine can help maintain quality of life and delay the need for full-time care in some patients.
- Memantine is available as immediate-release tablets and solution and extended-release capsules for once-daily dosing. Memantine is often slowly increased, and titration packs exist for both the generic and brand.

Off-label uses of memantine, supported by varying levels of evidence, include treatment of Parkinson's disease dementia, dementia with Lewy bodies, prevention of neurocognitive toxicity in patients undergoing whole brain radiation therapy, and management of trichotillomania and skin picking disorder.

Definitions

"Activities of Daily Living (ADLs)" refers to basic self-care tasks such as bathing, dressing, toileting, transferring, continence, and feeding.

"Alzheimer's disease" is a progressive neurodegenerative disorder characterized by cognitive decline, memory loss, and changes in behavior and personality.

"Dementia with Lewy bodies" is a type of progressive dementia characterized by the development of abnormal deposits of a protein called alpha-synuclein in the brain.

"NMDA receptor" refers to the N-methyl-D-aspartate receptor, an ionotropic glutamate receptor involved in synaptic transmission, plasticity, and excitotoxicity. Overstimulation of NMDA receptors may lead to neuronal cell death.

"Parkinson's disease dementia" refers to a decline in thinking and reasoning that develops in many people with Parkinson's disease at least a year after diagnosis.

"Skin picking disorder" (also known as excoriation disorder) is a mental health condition characterized by repeated picking at one's own skin.

"Trichotillomania" is a mental disorder characterized by recurrent, irresistible urges to pull out hair from the scalp, eyebrows, or other areas of the body.

Medical Necessity Criteria for Initial Authorization

The Plan considers Memantine (Namenda) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has ONE (1) of the following diagnoses or conditions:
    a. Moderate-to-severe Alzheimer's disease; *or*
    b. Parkinson's disease dementia or dementia with Lewy bodies; *or*
    c. Brain metastases requiring whole brain radiation therapy (for prevention of neurocognitive toxicity); *or*
    d. Trichotillomania or skin picking disorder (excoriation disorder); *AND*
3. Memantine (Namenda) is prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature (i.e., dose does not exceed 20 mg per day for immediate-release or 28 mg per day for extended-release formulations).

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if recent clinical documentation (within the last 3 months) indicates the member is responding positively to therapy as evidenced by at least ONE (1) of the following, specific to their diagnosis:

1. Alzheimer's Disease:
    a. Improvement, slowing or stabilization of cognitive function compared to expected disease progression or as assessed by a validated cognitive assessment tool; *or*
    b. Maintenance of ability to perform activities of daily living (ADLs); *or*
    c. Reduction in behavioral/psychiatric symptoms (if applicable); *or*
    d. Global improvement as reported by the member, caregiver, or healthcare provider.
2. Parkinson's Disease Dementia or Dementia with Lewy Bodies:
    a. Improvement, slowing, or stabilization of cognitive function; *or*
    b. Improvement in behavioral symptoms; *or*
    c. Global improvement as reported by the member, caregiver, or healthcare provider.
3. Prevention of Neurocognitive Toxicity:
    a. Maintenance or improvement of cognitive function as assessed by appropriate neurocognitive testing; *or*

b. Improvement in quality of life measures; *or*

4. Trichotillomania and Skin Picking Disorder:
    a. Reduction in hair pulling or skin picking behaviors; *or*
    b. Improvement in quality of life measures.

Experimental or Investigational / Not Medically Necessary

Memantine (Namenda) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Management of attention deficit hyperactivity disorder (ADHD). One in a small (n=40) randomized controlled trial, methylphenidate produced a significantly better outcome of clinical global impression compared to memantine, with more side effects also occurring in the memantine versus methylphenidate group. Positive benefits with memantine for the management have only been seen in small, pilot and open-label studies in both adults and children. There are no high quality, large, randomized controlled studies to support the use of memantine (Namenda) for the management of ADHD.
- Management of autism spectrum disorders (ASD). There are no high quality, large, randomized controlled studies to support the use of memantine (Namenda) for the management of ASD. Studies assessing memantine in ASD have provided mixed results in a small number of participants. More high quality data is needed to support use in this indication.
- Management of generalized anxiety disorder. There are no high quality, large, randomized controlled studies to support the use of memantine (Namenda) for the management of GAD. One small (n=7 with GAD) open-label study found that those with GAD were non-responders to memantine.
- Management of major depressive disorder (MDD). In several randomized, double-blind clinical trials assessing memantine (Namenda) compared to placebo and/or standard of care, there is a consistent lack of clinically and statistically significant improvement in depression symptoms. There is no high quality data to support the safety and efficacy of memantine (Namenda) for the management of MDD. Treatment of bipolar disorder. There is inconsistent data amongst studies assessing memantine (Namenda) compared to standard of care or placebo for various symptoms related to bipolar disorder. One larger study combined two 12-week randomized controlled studies found no improvement in cognitive function in those with bipolar disorder amongst those taking memantine as add-on therapy versus placebo. Studies showing positive results with memantine were smaller (n=35-38) and/or open-label or single-arm studies.
- Treatment of mild Alzheimer's disease. Memantine (Namenda) has only been studied and approved for those with moderate-to-severe Alzheimer’s disease dementia.
- Treatment of obsessive-compulsive disorder (OCD), without comorbid trichotillomania or skin-picking disorder. There is inconsistent data amongst studies assessing memantine (Namenda) compared to standard of care or placebo for various symptoms related to OCD. While some studies found a benefit, many do not identify a difference in OCD rating scales

between memantine (Namenda) and placebo or standard of care. Larger, more high quality studies are needed to identify a stronger trend in benefit amongst those with OCDTreatment of post-traumatic stress disorder (PTSD). Only one small (n=4) open-label pilot study was identified. There are no high quality, large, randomized controlled studies to support the use of memantine (Namenda) for the management of PTSD.

- Treatment of schizophrenia. While there are studies showing beneficial effects of memantine (Namenda) as adjunct/adjuvant therapy for the management of schizophrenia, more studies are needed to support the safety and efficacy of memantine (Namenda) for this indication.
- Treatment of vascular dementia without comorbid Alzheimer's disease. While there are studies showing beneficial effects of memantine (Namenda) on vascular dementia, more studies are needed to support the safety and efficacy of memantine (Namenda) for this indication.

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