## Clinical Guideline

# oscar

Oscar Clinical Guideline: Rivastigmine (Exelon) (PG212, Ver. 1)

# Rivastigmine (Exelon)

- Rivastigmine Tartrate Oral capsule
- Rivastigmine Transdermal Patch 24 Hour

#### Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

### 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.

Rivastigmine (Exelon) is a reversible acetylcholinesterase inhibitor indicated for the treatment of mild to severe dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. It is available in oral capsules and transdermal patch formulations.

#### 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 associated with Parkinson's disease**" is defined as dementia that develops at least one year after an established diagnosis of Parkinson's disease, with cognitive deficits that are severe enough to impact daily functioning.

"**Dementia of the Alzheimer's type**" refers to dementia that meets diagnostic criteria for probable Alzheimer's disease, as established by the National Institute on Aging and the Alzheimer's Association.

"**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.

"**Mild cognitive impairment**" refers to cognitive decline greater than expected for an individual's age and education level but that does not interfere notably with activities of daily life.

### Medical Necessity Criteria for Initial Authorization

The Plan considers **<u>Rivastigmine (Exelon)</u>** 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** of the following diagnoses or conditions:
  - a. dementia of the Alzheimer's type (Alzheimer's disease); **or**
  - b. mild to moderate dementia associated with Parkinson's disease; or
  - c. dementia with Lewy bodies (DLB); AND
- The diagnosis is supported by a validated cognitive assessment within the past 12 months (e.g., Mini-Mental State Examination [MMSE], Montreal Cognitive Assessment [MoCA]); AND
- 4. 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 12 mg per day for oral formulations or 13.3 mg/24 hours for transdermal patch).

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

#### Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if recent clinical documentation (within the last 6 months) indicates the member is responding positively to therapy as evidenced by at least one of the following:

- 1. Improvement or stabilization of cognitive function as assessed by a validated cognitive assessment tool; **OR**
- 2. Maintenance of ability to perform activities of daily living; OR
- 3. Reduction in behavioral or psychiatric symptoms (if applicable); OR
- 4. Global improvement as reported by the member, caregiver, or healthcare provider.

#### Experimental or Investigational / Not Medically Necessary

Rivastigmine (Exelon) 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:

- Anxiety Disorders.
- Delirium.
- Depression.
- Mild cognitive impairment.
- Psychosomatic Disorders.
- Schizophrenia.
- Traumatic Brain Injury (TBI).
- Vascular dementia.

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## **Clinical Guideline Revision / History Information**

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