PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

EXELON
(rivastigmine)

Status: CVS Caremark Criteria ***Ref # 85-A***
Type: Initial Prior Authorization ***Ref # 509-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Alzheimer's Disease

Exelon is indicated for the treatment of mild to moderate dementia of the Alzheimer's type (AD).
Exelon Patch is indicated for the treatment of dementia of the Alzheimer's type (AD). Efficacy has been demonstrated in patients with mild, moderate, and severe Alzheimer's disease.

Parkinson's Disease Dementia

Exelon and Exelon Patch are also indicated for the treatment of mild to moderate dementia associated with Parkinson's disease (PDD).

Compendial Uses

Dementia with Lewy bodies[3, 7, 8]

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has any of the following diagnoses: A) dementia of the Alzheimer's type, B) mild to moderate dementia associated with Parkinson's disease, C) dementia with Lewy bodies

AND

- If the request is for continuation of therapy, the medication continues to provide benefit to the patient
  [Note: If slowing decline of cognitive function is no longer a goal, or if the patient is rapidly declining, treatment with the medication is no longer appropriate.]
  OR
- The diagnosis is supported by a validated cognitive assessment within the past 12 months

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Exelon (rivastigmine) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease[1]; Exelon Patch is indicated for the treatment of dementia of the Alzheimer's type (AD) and for the treatment of mild to moderate dementia associated with Parkinson's disease (PDD).[2]

According to the American Academy of Neurology (AAN) guidelines on the treatment of dementia with Lewy bodies (DLB), Exelon may also be effective in improving cognitive function in patients with DLB, although the magnitude of the benefits is modest.[3, 7, 8]

Prior to initiating or renewing Exelon therapy, patients should undergo a comprehensive cognitive assessment. The comprehensive cognitive assessment should include evaluation with a validated cognitive assessment test that utilizes a standardized scale. Tests commonly used in clinical practice for Alzheimer's dementia are the Mini-Mental State Exam (MMSE-adjusted for age/education), the Alzheimer's Disease Assessment Scale, Cognitive Subsection (ADAS-Cog), or

the Blessed Information-Memory Concentration Test (BIMC).[1-6] For Parkinson's Disease patients, both the Cambridge Cognitive Examination (CAMCog) and MMSE have been studied to assess dementia and both had similar sensitivities. Although the MMSE is quicker to administer than the CAMCog, the CAMCog was more specific than the MMSE. The CAMCog includes all items of the MMSE and covers additional domains.[7] This assessment should have been completed within the previous 6 months for patients new to Exelon therapy and at least annually for patients who are continuing therapy, to allow clinicians to evaluate whether the drug continues to provide benefit to the patient.[1-6]

Exelon's effect may lessen as the disease process advances. There is no evidence that Exelon alters the course of the dementing process. If slowing decline of cognitive function is no longer a goal, or if the patient is rapidly declining, treatment with Exelon is no longer appropriate.[1-6]

REFERENCES

1. Rivastigmine Capsules [package insert]. Berlin, CT: Breckenridge Pharmaceutical, Inc. June 2020.
2. Exelon Patch [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. June 2020.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed May 5, 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed May 5, 2021.
5. Rabins P, Blacker D, Rovner B. Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias, Second Edition. *Am J Psychiatry*. 2007; 164(12S):1-56.
6. Qaseem A, Snow V, Cross T, et al. Current Pharmacological Treatment of Dementia: A Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians. *An Intern Med* 2008; 148:370-378.
7. Miyasaki JM, Shannon K, Ravina B, et al. Practice Parameter: Evaluation and Treatment of Depression, Psychosis, and Dementia in Parkinson Disease. *Neurology* 2006; 66:996-1002.
8. McKeith I, Del Ser T, Spano P, et al. Efficacy of rivastigmine in dementia with Lewy bodies: a randomised, double-blind, placebo-controlled international study. *Lancet* 2000; 356:2031-2036.

Written by:	UM Development (LS)
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CRITERIA FOR APPROVAL

1	Does the patient have any of the following diagnoses: A) dementia of the Alzheimer's type, B) mild to moderate dementia associated with Parkinson's disease, C) dementia with Lewy bodies? [If no, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If no, then skip to question 4.]	Yes	No
3	Does the medication continue to provide benefit to the patient? [Note: If slowing decline of cognitive function is no longer a goal, or if the patient is rapidly declining, treatment with the medication is no longer appropriate.]	Yes	No

[No further questions.]

4	Is the diagnosis supported by a validated cognitive assessment within the past 12 months?	Yes	No

Mapping Instructions (85-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: – Dementia of the Alzheimer's type – Mild to moderate dementia associated with Parkinson's disease – Dementia with Lewy bodies Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Go to 4	
3.	Approve, 36 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when it continues to provide benefit to you. Your request has been denied based on the information we have. [Short Description: No continued benefit]
4.	Approve, 36 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had an assessment in the past 12 months that supports your condition. Your request has been denied based on the information we have. [Short Description: No recent assessment]

Mapping Instructions (509-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: – Dementia of the Alzheimer's type – Mild to moderate dementia associated with Parkinson's disease – Dementia with Lewy bodies Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Go to 4	
3.	Approve, 12 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when it continues to provide benefit to you. Your request has been denied based on the information we have. [Short Description: No continued benefit]
4.	Approve, 12 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had an assessment in the past 12 months that supports your condition. Your request has been denied based on the information we have. [Short Description: No recent assessment]