Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE:	**Cholinesterase Inhibitors *and N-Methyl D-Aspartate Receptor Antagonist***
DEPARTMENT:	**Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE:	***November 2001 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2017*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ]HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for cholinesterase inhibitor and N-methyl-D-aspartate receptor antagonist drugs.

Donepezil (Aricept®) is indicated for the treatment of dementia of the Alzheimer's type. Efficacy has been demonstrated in patients with mild, moderate, and severe Alzheimer's disease.

Galantamine (Razadyne®/Razadyne ER®) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.

Rivastigmine tartrate oral capsule (Exelon®) and rivastigmine patch (Exelon® Patch) are indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease.

Memantine (Namenda®) and, memantine extended release (Namenda XR®), and memantine extended release/donepezil (Namzaric™) are indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

These agents do not cure the disease or reverse the disease process; however, they can improve and maintain the functional status of the members.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The cholinesterase inhibitor and N-methyl-D-aspartate receptor antagonist drugs are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective header:

1. For Cholinesterase inhibitors for mild to moderate Alzheimer's Dementia (Aricept, Galantamine, Exelon):

- Must be age 18 years or older
    - For Commercial members only, donepezil 5mg and donepezil 10mg are covered without a prior authorization for ages 50 years or older
- Must have a primary diagnosis of Alzheimer's dementia
- Must have at least one of three of the following characteristics:
    - Memory Loss
    - Other cognitive changes
    - Mood/behavior changes

2. For Exelon (rivastigmine) for Parkinson's disease:

- Must be age 18 years or older
- Must have a diagnosis of mild to moderate dementia associated with Parkinson's disease
- Must have at least one of three of the following characteristics: memory loss, other cognitive changes, or mood/behavior changes Criteria

3. For N-Methyl-D-Aspartate Receptor Antagonist (Namenda, Namenda XR, and Namzaric):

- Must be age 18 years or older
- Must have a primary diagnosis of moderate to severe Alzheimer's dementia
- Must be having difficulty with basic activities of daily living or be fully dependent
- Must have at least one of three of the following characteristics:
    - Memory loss
    - Other cognitive changes
    - Mood/behavior changes

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Aricept [prescribing information].Woodcliff Lake, NJ: Eisai Inc.; August 2013.
2. Exelon [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October2013.
3. Exelon Patch [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2013.
4. Namenda [prescribing information]. St. Louis, MO: Forest Pharmaceuticals, Inc.; October 2013.
5. Namenda XR [prescribing information]. St. Louis, MO: Forest Pharmaceuticals, Inc.; September 2014.
6. Razadyne ER [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2013.
7. American Psychiatric Association Diagnostic and Statistical Manual, 4th ed. *APA Press.* Washington DC, 1994.
8. Folstein MF, Folstein SE, McHugh PR. Mini-mental state: A practical method for grading the cognitive state of members for the clinician. *J Psychiatr Rec*. 1975; 12:189-198.
9. Mohs R. ADAS-Cog: what, why and how? *Alzheimer Insight Online.* Vol:3(1).
10. Doraiswamy PM, Bieber F, Kaiser L, et al. The Alzheimer's disease assessment scale: patterns and predictors of baseline cognitive performance in multicenter Alzheimer's disease trials. *Alzheimer Dis Assoc Disord*. 2001; 15(4):174-83.

11. Exelon in PaRkinson's disEaSe dementia Study (EXPRESS). *New England Journal of Medicine*. December 9, 2004; Volume 351:2509-2518.
12. Namzaric [Package Insertprescribing information]. Forest Pharmaceuticals. Dublin, Ireland. December 2014.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17*