Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 7/31/2018**
Policy Number:	**Effective Date: 01/2018** **Revision Date: 07/18/2018**
Policy Name:	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PMN.101 Rivastigmine (Exelon)

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Rivastigmine (Exelon)

Reference Number: PA.CP.PPA.22
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

Coding Implications
Revision Log

Formatted: Font: 18 pt, Font color: Auto

Description
Rivastigmine (Exelon®) is an acetylcholinesterase inhibitor.

FDA approved indication
Exelon is indicated for treatment of

- Mild to moderate dementia of the Alzheimer's type (AD)*
- Mild to moderate dementia associated with Parkinson's disease (PDD)

**Exelon patch is also indicated for treatment of severe dementia of AD.*

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness ® that Exelon is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Alzheimer's Disease (must meet all)**:**

1. Diagnosis of Alzheimer's disease;
2. Member meets one of the following (a or b):
   a. Failure of ≥ 3 month trial of donepezil at doses ≥ 10 mg/day or galantamine 24 mg/day;
   b. If member cannot take donepezil and galantamine due to intolerance or contraindication(s), failure of ≥ 3 month trial of memantine at doses ≥ 20 mg/day, unless member experiences clinically significant adverse effects or has contraindications to memantine;
3. Request does not exceed 12 mg per day (oral) or 13.3 mg/24 hours (transdermal).

Approval duration: 12 months

B. Parkinson's Disease Dementia (must meet all):

1. Diagnosis of Parkinson's disease dementia;
2. Failure of ≥ 3 month trial of donepezil at doses ≥ 10 mg/day, unless member experiences clinically significant adverse effects or has contraindication(s) to donepezil;
3. Request does not exceed 12 mg per day (oral) or 13.3 mg/24 hours (transdermal).

Approval duration: 12 months

C. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit, or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 12 mg per day (oral) or 13.3 mg/24 hours (transdermal).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months or duration of request (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
AD: Alzheimer's disease
FDA: Food and Drug Administration
PDD: Parkinson's disease dementia
PDL: preferred drug list

V. Dosage and Administration

- Exelon capsules
  - Exelon should be taken with meals in divided doses in the morning and evening.
  - Alzheimer's disease
    - Initial dose: Initiate treatment with 1.5 mg twice a day.
    - Dose titration: After a minimum of 2 weeks, if tolerated, increase dose to 3 mg twice a day and further to 4.5 mg twice a day and 6 mg twice a day if tolerated with a minimum of 2 weeks at each dose.
  - Parkinson's disease dementia
    - Initial dose: Initiate treatment with 1.5 mg twice a day.
    - Dose titration: After a minimum of 4 weeks, if tolerated, increase dose to 3 mg twice a day and further to 4.5 mg twice a day and 6 mg twice a day if tolerated with a minimum of 4 weeks at each dose.
- Exelon patches
  - Exelon patch should be applied on intact skin for a 24-hour period; replace with a new patch every 24 hours.

- Initial dose: Initiate treatment with 4.6 mg/24 hours Exelon patch.
- Dose titration: After a minimum of 4 weeks, if tolerated, increase dose to 9.5 mg/24 hours, which is the minimum effective dose. Following a minimum additional 4 weeks, may increase dosage to maximum dosage of 13.3 mg/24 hours.
  - Mild to moderate Alzheimer's disease and Parkinson's disease dementia: Exelon patch 9.5 mg/24 hours or 13.3 mg/24 hours once daily.
  - Severe Alzheimer's disease: Exelon patch 13.3 mg/24 hours once daily.
- For treatment interruption longer than 3 days, retitrate dosage starting at 4.6 mg per 24 hours.
- Consider dose adjustments in patients with:
  - Mild to moderate hepatic impairment;
  - Low (<50 kg) body weight.

VI. Product Availability

Exelon capsules are available in the following strengths: 1.5 mg, 3 mg, 4.5 mg, and 6 mg.

Exelon patches are available in the following strengths: 4.6 mg/24 hours, 9.5 mg/24 hours, and 13.3 mg/24 hours.

VII. References

1. Exelon Patch Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2016. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exelonpatch.pdf. Accessed November 28, 2016.
2. Exelon. Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2016. Available at: https://dailymed.nlm.nih.gov/. Accessed November 28, 2016.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com/.
4. Qaseem A, Snow V, Cross JT, Forciea MA, Hopkins R, Shekelle P, et al. Current Pharmacologic Treatment of Dementia: A Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians. Ann Intern Med. 2008;148:370-378.
5. American Academy of Neurology. Practice Parameter: evaluation and treatment of depression, psychosis, and dementia in Parkinson disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. https://www.aan.com/guidelines/. Accessed November 28, 2016.

Reviews, Revisions, and Approvals	Date	Approval Date
This policy is being retired and replaced by the following policy: **PA.CP.PMN.101 Rivastigmine (Exelon)**	7/18	