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

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