Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Aptiom (eslicarbazepine acetate)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2014 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *January 2018*

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 Aptiom (eslicarbazepine acetate).

Aptiom (eslicarbazepine acetate) is indicated for monotherapy or adjunctive treatment of partial-onset seizures.

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, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Aptiom (eslicarbazepine acetate), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist
- Must be age 4 years or older
- Must have a diagnosis of partial-onset seizures
- Must be using Aptiom as monotherapy or adjunctive therapy to other anti-epileptic drugs (AEDs)
    - Must not be using with oxcarbazepine as adjunctive therapy
- Must have had an inadequate response or intolerance to at least 2 generic antiepileptic medications for both monotherapy or adjunctive therapy indication
- Must have documentation of baseline transaminase and bilirubin levels

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Level Limit	
200mg, 400mg	30 tablets per 30 days
600mg, 800mg	60 tablets per 30 days

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

REFERENCES

1. Aptiom [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc. September 2017.
2. Elger C, Halasz P, Maia J, et al. Efficacy and safety of eslicarbazepine acetate as adjuctive treatment in adults with refractory partial-onset seizures: A randomized, double-blind, placebo-controlled, parallel-group phase III study. Epilepsia 2009;50:454-63.
3. Ben-Menachem E, Gabbai AA, Hufnagel A, et al. Eslicarbazepine acetate as adjunctive therapy in adult patients with partial epilepsy. Epilepsy Res 2010;89:278-85.

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	*02/16, 02/17*
Criteria Update	*01/18*