

Aptiom (eslicarbazepine acetate)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Partial-onset seizures, also known as focal seizures, start in a specific area or 'focus' in the brain. These seizures can further be categorized into two types: focal onset aware seizures, where the individual remains conscious and aware throughout the seizure, and focal onset impaired awareness seizures, where the individual's awareness is impacted during the seizure. The specific symptoms of a partial-onset seizure can vary widely depending on the area of the brain where the seizure originates.

Aptiom (eslicarbazepine acetate) is a prescription medication used to treat partial-onset seizures in patients aged 4 years and older. Eslicarbazepine acetate works by stabilizing the electrical activity in the brain to prevent seizures. It may be used alone or as an adjunctive therapy, meaning it can be used in combination with other anti-seizure medications. While Aptiom (eslicarbazepine acetate) can help to manage the symptoms of partial-onset seizures, it does not cure the underlying condition causing the seizures. The goal of Aptiom (eslicarbazepine acetate) therapy, like that of many anti-seizure medications, is to reduce the frequency and severity of seizures, improving the patient's quality of life.

Definitions

“**Antiepileptic Drugs**” Medications used to prevent or reduce the severity and frequency of seizures in various types of epilepsy.

“**Partial seizures**” are an older term that has been used to describe seizures that start in a specific part of the brain. The term "partial" reflects the fact that these seizures are localized to a specific area at the onset.

“**Focal seizures**” is a term that has been more recently adopted by the International League Against Epilepsy, replacing "partial seizures." This term is more descriptive of the fact that the seizure originates from a specific 'focus' in the brain.

“**Partial-onset Seizures (Focal Seizures)**” are seizures that begin in a specific region or 'focus' of the brain. They can be further categorized into:

- **Focal Onset Aware Seizures:** Seizures where the individual remains conscious and aware throughout the event.
- **Focal Onset Impaired Awareness Seizures:** Seizures that impact an individual's consciousness or awareness during the event.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Aptiom (eslicarbazepine acetate)** medically necessary when **ALL** of the following criteria are met:

1. The medication is prescribed by or in consultation with a neurologist or epilepsy specialist; **AND**
2. The member is 4 years of age or older; **AND**
3. The member has a diagnosis of focal seizures (i.e., partial-onset seizures, partial seizures); **AND**
4. The member has documented evidence of inadequate seizure control with at least two alternate antiepileptic drugs at maximally tolerated doses. These may include, but are not limited to, the following:
 - a. Carbamazepine; **and/or**
 - b. Divalproex; **and/or**
 - c. Fosphenytoin; **and/or**
 - d. Lamotrigine; **and/or**
 - e. Levetiracetam; **and/or**
 - f. Oxcarbazepine; **and/or**
 - g. Phenobarbital; **and/or**

- h. Phenytoin; **and/or**
 - i. Pregabalin; **and/or**
 - j. Topiramate; **and/or**
 - k. Valproic acid; **and/or**
 - l. Zonisamide; **AND**
5. Aptiom (eslicarbazepine acetate) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines.

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if the member has recent (within the last 3-months) clinical chart documentation demonstrating **ALL** of the following criteria:

1. The requested medication is prescribed by or in consultation with a neurologist or epilepsy specialist; **AND**
2. The member has experienced a documented improvement in seizure control validated by clinical documentation showing:
 - a. Decreased seizure frequency from baseline; **OR**
 - b. Decreased seizure severity from baseline; **OR**
 - c. Decreased seizure duration from baseline.

Experimental or Investigational / Not Medically Necessary

Aptiom (eslicarbazepine acetate) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Bipolar 1 Disorder
- Fibromyalgia
- Migraine
- Neuropathic Pain
- Other forms of Epilepsies
- Painful Diabetic Neuropathy (PDN)
- Postherpetic Neuralgia

References

1. Aptiom (eslicarbazepine) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; March 2019.
2. Fisher R.S., et al.: Operational classification of seizure types by the International League Against Epilepsy: position paper of the ILAE commission for classification and terminology. *Epilepsia* 2017; 58 (4): pp. 522-530.
3. Kanner AM, Ashman E, Gloss D, Harden C, Bourgeois B, Bautista JF, Abou-Khalil B, Burakgazi-Dalkilic E, Park EL, Stern J, Hirtz D, Nespeca M, Gidal B, Faught E, French J. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the American Epilepsy Society and the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Epilepsy Curr.* 2018 Jul-Aug; 18(4):269-278. PMID: 30254528; PMCID: PMC6145395.
4. Krumhold A., et al.: Evidence-based guideline: management of an unprovoked first seizure in adults. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology* 2015; 84 (16): pp. 1705-1713.
5. Pack A.M., et al.: Epilepsy overview and revised classification of seizures and epilepsies. *Continuum (Minneap Minn)* 2019; 25 (2): pp. 306-321.

Clinical Guideline Revision / History Information

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