

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 partial seizures, focal seizures, or focal-onset seizures, start in a specific area or 'focus' in the brain. There are several subtypes of focal seizures including: focal aware seizures, focal impaired awareness seizures, focal motor seizures, focal nonmotor seizures and focal bilateral tonic-clonic seizures. The specific symptoms of a partial-onset seizure can vary widely depending on the area of the brain where the seizure originates. Focal epilepsy may be due to a focal brain pathology (due to a known syndrome or genetic cause), or be due to an unknown cause. Focal seizures can be managed with both narrow spectrum (e.g., carbamazepine, gabapentin, oxcarbazepine, phenytoin, phenobarbital, primidone, tiagabine) and broad spectrum anti-seizure medication (e.g., clobazam, felbamate, lacosamide, lamotrigine, levetiracetam, valproate, zonisamide) including Aptiom (eslicarbazepine acetate).

Aptiom (eslicarbazepine acetate) is a prescription medication used to treat partial-onset seizures in those 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.

“Focal-onset seizures (partial-onset 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 (2) alternate antiepileptic drugs at maximally tolerated doses. These may include, but are not limited to, the following:
 - a. Carbamazepine; *and/or*
 - b. Divalproex (use in those 9 years of age and younger is off-label); *and/or*
 - c. Fosphenytoin; *and/or*
 - d. Lacosamide; *and/or*
 - e. Lamotrigine; *and/or*
 - f. Levetiracetam; *and/or*
 - g. Methsuximide; *and/or*

- h. Oxcarbazepine; *and/or*
 - i. Phenobarbital; *and/or*
 - j. Phenytoin; *and/or*
 - k. Pregabalin; *and/or*
 - l. Primidone; *and/or*
 - m. Tiagabine (use in those 11 years of age and younger is off-label); *and/or*
 - n. Topiramate; *and/or*
 - o. Valproate (use in those 9 years of age and younger is off-label); *and/or*
 - p. Valproic acid (use in those 9 years of age and younger is off-label); *and/or*
 - q. Zonisamide (use in those 15 years of age and younger is off-label); **AND**
5. Aptiom (eslicarbazepine acetate) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

If the above prior authorization criteria are met, the requested product will be authorized for up to a lifetime.

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. In a 3- week multicentre, double-blind, randomized controlled study (n=160) studying Aptiom (eslicarbazepine acetate) versus placebo (NCT01822678, NCT01824602, NCT01825837), there was not a significant difference between groups in the primary outcome of change from baseline in the Young Mania Rating Scale. While the secondary outcomes trended towards significant, they were not powered to see a difference. There is not enough data to support the efficacy and safety of Aptiom (eslicarbazepine acetate) for this indication.
- Fibromyalgia. In an unpublished randomized double-blind controlled study (NCT01820585) in those with fibromyalgia, Aptiom (eslicarbazepine acetate) did not appear to significantly improve pain management compared to placebo. A meta-analysis assessing the safety and tolerability of Aptiom (eslicarbazepine acetate) for neurological disorders only found one randomized controlled study (described above) for this indication, which did not provide more evidence.
- Migraine. In an unpublished randomized double-blind controlled study (NCT01820559) in those with migraines, Aptiom (eslicarbazepine acetate) did not appear to significantly improve migraine frequency compared to placebo. A literature review of Aptiom (eslicarbazepine acetate) for the management of neuropathic pain, headache and cranial neuralgia did not find sufficient evidence to recommend Aptiom (eslicarbazepine acetate) for any of these indications, including headaches.

- Neuropathic Pain including Painful Diabetic Neuropathy (PDN) and postherpetic neuralgia. In two unpublished randomized double-blind controlled study (NCT00980746, NCT01129960) in those with PDN, Aptiom (eslicarbazepine acetate) did not appear to significantly improve mean daily pain scores compared to placebo. One case study (n=1) found that one individual's PDN was managed by a combination of medication neuropathic pain including gabapentin, tramadol, and Aptiom (eslicarbazepine acetate). In two unpublished randomized double-blind controlled study (NCT01124097, NCT00981227) in those with postherpetic neuralgia, Aptiom (eslicarbazepine acetate) potentially trended toward improved pain management compared to placebo, however statistical point estimates were not published. There is not enough data to support the efficacy and safety of Aptiom (eslicarbazepine acetate) for this indication. Other forms of epilepsies, not included in this policy.

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Clinical Guideline Revision / History Information

Original Date: 9/21/2023

Reviewed/Revised: 12/19/2024, 12/01/2025