Oscar Clinical Guideline: Briviact (brivaracetam) Tablet, Solution (PG172, Ver. 3)

Briviact (brivaracetam) Tablet, Solution

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 medications (e.g., clobazam, felbamate, lacosamide, lamotrigine, levetiracetam, valproate, zonisamide) including Briviact (brivaracetam).

Briviact (brivaracetam) is a prescription medication that is used to treat partial-onset seizures. It is indicated for use in those 1 month of age and older. The exact mechanism by which Briviact (brivaracetam) exerts anti-seizure activity is unknown. However, Briviact (brivaracetam) binds to the synaptic vesicle protein 2A (SV2A) in the brain, which is thought to play a role in the release of

neurotransmitters. By doing so, it helps to reduce the excessive electrical signals in the brain that can lead to seizures.

Briviact (brivaracetam) can be used alone or in conjunction with other anti-seizure medications. The exact dosage and administration of Briviact (brivaracetam) will depend on the specific needs of the individual, including their age, weight, and overall health status.

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 Briviact (brivaracetam) 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 has a diagnosis of focal seizures (i.e., partial-onset seizures, partial seizures); *AND*
3. 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; *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; *and/or*
n. Topiramate; *and/or*
o. Valproate; *and/or*
p. Valproic acid; *and/or*
q. Zonisamide; *AND*

4. IF the request is for Briviact (brivaracetam) 10mg/mL Solution, documentation indicating the member's inability or unwillingness to take the tablet form; *AND*
5. Briviact (brivaracetam) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

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

Experimental or Investigational / Not Medically Necessary

Briviact (brivaracetam) 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:

- Neuropathic Pain. While studies have been conducted with Briviact (brivaracetam) for the management of post-herpetic neuralgia and spinal cord injury-related neuropathic pain, these studies are very small (ranging from 14-152 participants) and are of low quality. Briviact (brivaracetam) does not have FDA approval for any form of neuropathic pain.
- Other forms of Epilepsies. Briviact (brivaracetam) has not been studied and found to be safe and effective for the management of other forms of epilepsy other than focal/focal-onset, partial, partial-onset seizures.
- Postherpetic Neuralgia. The only study assessing Briviact (brivaracetam) for postherpetic neuralgia was small (n=152) and did not result in a significant improvement in average pain intensity between placebo and any dose of Briviact (brivaracetam). Briviact (brivaracetam) does not have FDA approval for postherpetic neuralgia.
- Spinal Cord Injuries. The only study assessing Briviact (brivaracetam) was very small (n=14) and found a small reduction in pain and a high rate of side effects (73% and 33% for Briviact [brivaracetam] and placebo, respectively) for spinal code injury-related neuropathic pain. Given

the low quality data and small sample size, more studies would need to be conducted to evaluate safety and efficacy for this indication.

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Clinical Guideline Revision / History Information

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