Oscar Clinical Guideline: Briviact (brivaracetam) Tablet, Solution (PG172, Ver. 5)

Briviact (brivaracetam) Tablet, Solution

- Briviact (brivaracetam) tablet
- Briviact (brivaracetam) oral solution
- Briviact (brivaracetam) injection, 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.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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.

"[s]" indicates state mandates may apply.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Focal Seizure

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 is unable to use, or has tried and failed (e.g., inadequate seizure control), TWO (2) alternate antiepileptic drugs as applicable to the member's age (see Appendix A, Table 3). These may include, but are not limited to, the following[s]:
    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 sodium; *and/or*
    p. valproic acid; *and/or*
    q. zonisamide; *AND*
4. IF the request is for Briviact (brivaracetam) 10mg/mL oral solution, documentation indicating the member's inability or unwillingness to take the tablet form[s]; *AND*

5. IF the request is for Briviact (brivaracetam) injection for intravenous (IV) use, documentation indicating oral Briviact (brivaracetam) administration is not feasible (e.g., esophageal condition or intraoral infection, recent oral or neck surgery, reliance on gastrostomy tube, status epilepticus, myasthenia gravis, or other neuromuscular condition)[s]; *AND*
6. IF the request is for brand Briviact, the member is unable to use, or has tried and failed the corresponding generic brivaracetam from ONE manufacturer, when available[s]; *AND*
7. Briviact (brivaracetam) 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 for the requested indication.

   The requested medication is being used within the Plan's Quantity Limit of:

   - *Briviact (brivaracetam) tablets: 60 tablets every 30 days; or*
   - *Briviact (brivaracetam) oral solution: 600 mL every 30 days.*

If the above prior authorization criteria are met, the requested product will be authorized for up to ONE of the following:[s]

- Briviact (brivaracetam) tablet or Briviact (brivaracetam) oral solution: lifetime*; or*
- Briviact (brivaracetam) injection, solution: 12 months.

Experimental / Investigational, or unproven[s]

Briviact (brivaracetam) for any other use is considered experimental, investigational, or unproven. Non-covered uses 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.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
J3490	Briviact (brivaracetam) 50 mg/5 mL injection, solution Unclassified drugs

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus

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Appendix A

Table 3: Antiepileptic Age-Specific Dosing and Formulation Guidance

Anti-epileptic Agent	FDA Approved Age-Specific Guidance (Seizure Specific Indications)	Dosage Formulations
brivaracetam (Briviact)	1 month of age and older	Tablet; oral solution; intravenous (IV) injection
carbamazepine (Tegretol)	1 year of age and older (immediate release) 6 years of age and older (extended-release tablets) 1 year of age and older (extended-release capsules)	Tablet; chewable tablet; oral suspension; extended-release tablet; extended-release capsule
divalproex (Depakote, Depakkote ER,	10 years of age and older	Delayed-release tablet; delayed-release sprinkle capsule; extended-release tablet

Anti-epileptic Agent	FDA Approved Age-Specific Guidance (Seizure Specific Indications)	Dosage Formulations
Depakote Sprinkle)		
fosphenytoin (Cerebyx)	All ages	IV/intramuscular (IM) injection
lacosamide (Vimpat)	1 month of age and older (partial-onset seizures) 4 years of age and older (primary generalized tonic-clonic seizures)	Tablet; oral solution; IV injection
lamotrigine (Lamictal)	2 years of age and older (as adjunct: partial-onset, primary generalized tonic-clonic and generalized seizures of Lennox-Gastaut syndrome) 16 years of age and older (as monotherapy)	Tablet; chewable/dispersible tablet; orally disintegrating tablet; extended-release tablet
levetiracetam (Keppra)	12 years of age and older (juvenile myoclonic epilepsy) 6 years of age and older (primary generalized tonic-clonic seizures)	Tablet; oral solution; IV injection; extended-release tablet; tablet for oral suspension
methsuximide (Celontin)	All ages	Capsule
oxcarbazepine (Trileptal)	4 years of age and older (monotherapy: partial-onset seizures) 2 years of age and older (adjunct therapy: partial-onset seizures)	Tablet; oral suspension
phenobarbital	All ages	Tablet; oral elixir/solution; injection
phenytoin (Dilantin, Dilantin Infatabs, Phenytek, Phenytoin Infatabs)	All ages	Extended-release capsule; chewable tablet; oral suspension; injection
pregabalin (Lyrica)	1 month of age and older (adjunct therapy: partial onset seizures)	Capsule; oral solution

Anti-epileptic Agent	FDA Approved Age-Specific Guidance (Seizure Specific Indications)	Dosage Formulations
primidone (Mysoline)	1 month of age and older (generalized tonic-clonic seizures or complex partial seizures without prior treatment) 8 years of age and older (generalized tonic-clonic seizures or complex partial seizures already receiving other anticonvulsant therapy)	Tablet
tiagabine (Gabitril)	12 years of age and older	Tablet
topiramate (Eprontia, Qudexy XR, Trokendi XR, Topamax, Topamax Sprinkle)	2 years of age and older	Tablet; sprinkle capsule; extended-release capsule; oral solution
valproate sodium	10 years of age and older	Oral solution; IV injection
valproic acid	10 years of age and older	Capsule
zonisamide (Zonegran, Zonisade)	16 years of age and older	Capsule; oral suspension

Clinical Guideline Revision / History Information

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