Oscar Clinical Guideline: Fycompa (perampanel) (PG176, Ver. 2)

Fycompa (perampanel)

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, begin in a specific part of the brain. These seizures can be categorized into two types: simple and complex. Simple partial seizures typically do not cause loss of consciousness, while complex partial seizures may impair consciousness. Symptoms can vary widely depending on the area of the brain where the seizure originates.

- Fycompa (perampanel) is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older.

Primary Generalized Tonic-Clonic Seizures (PGTCS), previously known as grand mal seizures , involve the entire brain from the onset of the seizure. These seizures typically have two phases. The tonic phase involves a sudden loss of consciousness and muscle stiffening, while the subsequent clonic phase involves rapid muscle contractions or convulsions.

- Fycompa (perampanel) is indicated as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

Lennox-Gastaut Syndrome (LGS) is a severe form of epilepsy that typically begins in early childhood. It is characterized by multiple types of seizures, including atonic (drop attacks), tonic, atypical absence, and myoclonic seizures. Cognitive development is also often affected.

- While Fycompa has received orphan drug designation for the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS), it is not FDA-approved for this indication. Use for LGS is considered off-label and requires careful assessment of risks and benefits.

Members receiving Fycompa (perampanel) should be closely monitored for psychiatric and behavioral side effects, particularly during the titration phase and at higher doses. These effects may include irritability, anger, aggression, hostility, homicidal ideation, and suicidal thoughts or behaviors. Monitoring is especially critical during the first 6 weeks of therapy and after dose increases. If severe psychiatric symptoms occur, the dose should be reduced or the medication discontinued, and the member should be referred for psychiatric evaluation.

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.

"**Lennox-Gastaut Syndrome (LGS)**" is a rare and severe form of childhood-onset epilepsy characterized by multiple types of seizures and cognitive dysfunction. It typically begins between the ages of 2 and 6 and can be caused by various brain abnormalities or injuries, though in many cases its cause remains unknown.

"**Orphan Drug**" refers to a medicinal product designed for the prevention, diagnosis, or treatment of rare diseases or disorders. These are conditions that affect a small percentage of the population. In the United States, the Food and Drug Administration (FDA) defines an orphan drug as one "intended for the treatment, prevention, or diagnosis of a rare disease or condition, which is one that affects less than 200,000 persons in the US" or meets cost recovery provisions of the act.

"**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 **Fycompa (perampanel)** 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. **IF** the request is for Fycompa 0.5mg/mL Suspension, documentation indicating the member's inability or unwillingness to take the tablet form; ***AND***
3. Fycompa (perampanel) 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; ***AND***
4. The member has a diagnosis of a diagnosis of epilepsy and meets the medical necessity criteria for the applicable indication listed below:

Partial-onset Seizures (Focal Seizures)

4. The member is 4 years of age or older; ***AND***
5. The member has a diagnosis of focal seizures (i.e., partial-onset seizures, partial seizures); ***AND***
6. 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.

<u>Primary Generalized Tonic-Clonic Seizures</u>

4. The member is 12 years of age or older; ***AND***
5. The member has a diagnosis of primary generalized tonic-clonic seizures; ***AND***
6. 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. Phenobarbital; ***and/or***
    g. Phenytoin; ***and/or***
    h. Topiramate; ***and/or***
    i. Valproic acid.

<u>Seizures Associated with Lennox-Gastaut Syndrome</u>

4. The member has a diagnosis ofLennox-Gastaut Syndrome; ***AND***
5. 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. Cannabidiol; ***and/or***
    b. Clobazam; ***and/or***
    c. Clonazepam; ***and/or***
    d. Felbamate; ***and/or***
    e. Fenfluramine; ***and/or***
    f. Lamotrigine; ***and/or***
    g. Rufinamide; ***and/or***

h. Topiramate.

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

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

Fycompa (perampanel) 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:

- Alcohol Disorders.
- Amyotrophic Lateral Sclerosis (ALS).
- Bipolar Disorder (BD).
- Diabetic Neuropathies.
- Electroencephalography.
- Essential Tremor.
- Major Depressive Disorder (MDD).
- Neuropathic Pain.
- Other forms of Epilepsies.
- Parkinson's Disease (PD).
- Post Traumatic Stress Disorder (PTSD) .
- Prophylaxis of migraine headaches.

References

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Clinical Guideline Revision / History Information

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