Clinical Policy: Perampanel (Fycompa)

Reference Number: IL.ERX.PMN.156
Effective Date: 06.01.21
Last Review Date: 08.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Perampanel (Fycompa®) is a non-competitive α-amino-3-hydroxy-5-methyl-4- isoxazolepropionic acid (AMPA) glutamate receptor antagonist.

FDA Approved Indication(s)
Fycompa 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
- For adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions that Fycompa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Partial-Onset Seizures (must meet all)**:**

1. Diagnosis of partial-onset seizures;
2. Age ≥ 4 years;
3. Failure of 2 preferred alternatives (*see Appendix B for examples*) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 12 mg per day (1 tablet per day).

Approval duration: 12 months

B. Primary Generalized Tonic-Clonic Seizures (must meet all)**:**

1. Diagnosis of primary generalized tonic-clonic seizures;
2. Age ≥ 12 years;
3. Failure of 2 preferred alternatives (*see Appendix B for examples*) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Fycompa will be used as adjunctive therapy;
5. Dose does not exceed 12 mg per day (1 tablet per day).

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Fycompa for seizures and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 12 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
2. **Approval duration: Duration of request or 12 months (whichever is less);** or Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AMPA: α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Class	Examples	Dose Limit/ Maximum Dose
Anticonvulsants for partial seizures	carbamazepine (Tegretol®), gabapentin (Neurontin®), lamotrigine (Lamictal®), levetiracetam (Keppra®), oxcarbazepine (Trileptal®), phenytoin (Dilantin®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®), zonisamide (Zonegran®)	Varies according to the agent used
Anticonvulsants for tonic-clonic seizures	carbamazepine (Tegretol®), lamotrigine (Lamictal®), levetiracetam (Keppra®), phenytoin (Dilantin®), primidone (Mysoline®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®)	Varies according to the agent used

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): serious or life-threatening psychiatric and behavioral adverse reactions

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial-onset seizures	2 mg PO QHS (4 mg if on CYP3A4 enzyme- inducers). May increase based on clinical response and tolerability by increments of 2 mg QD, no more frequently than at weekly intervals. The recommended maintenance dose range is 8 mg to 12 mg QD, although some patients may respond to a dose of 4 mg QD.	12 mg/day
Primary generalized tonic-clonic	2 mg PO QHS (4 mg if on CYP3A4 enzyme- inducers). May increase based on clinical response and tolerability by increments of 2 mg QD, no more frequently than at weekly	12 mg/day

Indication	Dosing Regimen	Maximum Dose
seizures	intervals. The recommended maintenance dose is 8 mg QHS. Patients who are tolerating Fycompa at 8 mg QD and require further reduction of seizures may benefit from a dose increase up to 12 mg QD if tolerated.	

VI. Product Availability

- Tablets: 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg
- Oral suspension: 0.5 mg/mL

VII. References

1. Fycompa Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; February 2021. Available at www.fycompa.com. Accessed July 16, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 16, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 16, 2021.
4. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018; 91 (2)
5. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018; 91 (2)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21
3Q 2021 annual review: no significant changes; references reviewed and updated.	07.16.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.