

Clinical Policy: Perampanel (Fycompa)

Reference Number: HIM.PA.132

Effective Date: 12.01.17

Last Review Date:

[Revision Log](#)

Line of Business: Health Insurance Marketplace

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 aged 12 years 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

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

1. Diagnosis of partial-onset seizures;
2. Age \geq 12 years;
3. Dose does not exceed 12 mg/day.

Approval duration: 12 months

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

1. Diagnosis of primary generalized tonic-clonic seizures;
2. Age \geq 12 years;
3. Patient is receiving treatment with at least one other antiepileptic drug;
4. Dose does not exceed 12 mg/day.

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to HIM.PHAR.21 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 Centene benefit, 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 (e.g., improved seizure control, no inappropriate toxicity);
3. If request is for a dose increase, new dose does not exceed 12 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications(must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to HIM.PHAR.21 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 – HIM.PHAR.21 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

V. References

1. Fycompa Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; July 2017. Available at www.fycompa.com. Accessed August 16, 2017.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 20, 2016.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. URL: <http://www.clinicalpharmacology.com>. Accessed January 12, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.18.17	11.17

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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