Clinical Policy: Perampanel (Fycompa)

Reference Number: PA.CP.PMN.156
Effective Date: 10.17.18
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Revision Log

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 (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 PA Health & Wellness® that Fycompa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Partial-Onset Seizures (must meet 1 through 4, or 5)**:**

1. Diagnosis of partial-onset seizures;
2. Age ≥12 years;
3. Failure of 2 preferred alternatives (*see Appendix B for examples*) unless all are contraindicated or clinically significant adverse effects are experienced; and
4. Dose does not exceed 12 mg/day; or
5. Member is currently receiving Fycompa and is responding positively to therapy.

Approval duration: 12 months

B. Primary Generalized Tonic-Clonic Seizures (must meet 1 through 5, or 6)**:**

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

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 policies – PA.CP.PMN.53

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®), felbamate (Felbatol®), gabapentin (Neurontin®), lamotrigine (Lamictal®), levetiracetam (Keppra®), oxcarbazepine (Trileptal®), phenytoin (Dilantin®), tiagabine (Gabitril®), 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	Varies according to the agent used

Drug Class	Examples	Dose Limit/ Maximum Dose
	(Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®)	

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
Not applicable

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Partial-onset seizures	The recommended starting dosage is 2 mg once daily taken orally at bedtime (4 mg in patients on CYP3A4 enzyme-inducers). May increase based on clinical response and tolerability by increments of 2 mg once daily, no more frequently than at weekly intervals. The recommended maintenance dose range is 8 mg to 12 mg once daily, although some patients may respond to a dose of 4 mg daily.	12 mg/day
Primary Generalized Tonic-Clonic Seizures	The recommended starting dosage is 2 mg once daily taken orally at bedtime (4 mg in patients on CYP3A4 enzyme-inducers). May increase based on clinical response and tolerability by increments of 2 mg once daily, no more frequently than at weekly intervals. The recommended maintenance dose is 8 mg once daily taken at bedtime. Patients who are tolerating Fycompa at 8 mg once daily and require further reduction of seizures may benefit from a dose increase up to 12 mg once daily if tolerated.	12 mg/day

VI. Product Availability

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

VII. References

1. Fycompa Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; July 2017. Available at www.fycompa.com. Accessed April 4, 2018.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 4, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 4, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	