Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Fycompa® (Perampanel)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***May 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *October 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Fycompa® (perampanel).

Fycompa® (perampanel) is indicated for:

- Treatment in patients with partial onset seizures with or without secondarily generalized seizures
- Adjunct treatment of primary generalized tonic-clonic seizures

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process. The drug, Fycompa® (perampanel), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Partial Onset Seizures (with or without secondarily generalized seizures)**
   - Must be prescribed by a neurologist
   - Must be age 4 years and older
   - Must have a diagnosis of partial-onset seizures
   - Must have had an inadequate response or intolerance to at least TWO other antiepileptic drugs (AEDs)
   - Must have an evaluation by a psychiatrist prior to the use of Fycompa if the member has a history of psychiatric symptoms (including anger, aggression, hostility, irritability, suicidal ideation, and homicidal ideation) OR if the member is currently undergoing psychiatric treatment. These patients must also be followed concurrently by a psychiatrist while on Fycompa with chart documentation provided.

2. **Primary Generalized Tonic-Clonic Seizures**
   - Must be prescribed by a neurologist
   - Must be age 12 years and older
   - Must have a diagnosis of tonic-clonic seizures
   - Must have had an inadequate response or intolerance to at least TWO other AEDs
   - Must be using Fycompa as adjunctive therapy to other AEDs
   - Must have an evaluation by a psychiatrist prior to the use of Fycompa if the member has a history of psychiatric symptoms (including anger, aggression, hostility, irritability, suicidal ideation, and homicidal ideation) OR if the member is currently undergoing psychiatric treatment. These patients must also be followed concurrently by a psychiatrist while on Fycompa with chart documentation provided.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy. For members with a history of psychiatric symptoms OR members with a current psychiatric treatment, chart documentation must be provided to show current evaluation by a psychiatrist.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Tablet	30 tablets per 30 days
Suspension	720mL per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Fycompa [prescribing information]. Eisai, Inc. Woodcliff Lake, NJ. September 2018.
2. French JA, Krauss GL, Biton V, et al. Adjunctive perampanel for refractory partial-onset seizures: Randomized phase III study 304. Neurology 2012; 79:589-596.
3. French JA, Krauss GL, Steinhoff BJ, et al. Evaluation of adjunctive perampanel in patients with refractory partial-onset seizures: Results of randomized phase II study 305. Epilepsia 2012; August [online publication].
4. Krauss GL, Serratossa JM, Villanueva V, et al. Randomized phase III study 306: Adjunctive perampanel for refractory partial-onset seizures. Neurology 2012; 78:408-1415.
5. Tegretol [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; January 2014
6. Dilantin [prescribing information]. New York, NY: Park-Davis, Inc.; August 2014.
7. Depakene [prescribing information]. North Chicago, IL; AbbVie Inc.; November 2014.
8. Depakote [prescribing information]. North Chicago, IL; AbbVie Inc.; November 2014.
9. Mysoline [prescribing information]. Alsio Viejo, CA: Valeant Pharmaceuticals; March 2009.
10. Keppra [prescribing information]. Smyrna, GA: UCB, Inc; 2009.
11. Lamictal [package insert]. Research Triangle Park, NC: GlaxoSmithKline;2014.
12. Topamax [package insert]. Titusville, NJ: Janssen Ortho, LLC; 2014.
13. French, J. Krauss, G et al. Adjunctive Perampanel for Treatment of Drug-Resistant Primary Generalized Tonic-Clonic Seizures in Patienets with Idiopathic Generalized Epilepsy: A Double

Blind, Randomized, Placebo-Controlled Phase III Trial. Presented at: 68th Annual Meeting of the American Epilepsy Society; December 5-9, 2014; Seattle, WA. [poster]

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria Update	*09/17*
Age Indication Update	*10/18*