Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Potiga (ezogabine)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2012 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 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 Potiga (ezogabine).

Potiga (ezogabine) is indicated for the adjunctive treatment of partial-onset seizures in patients aged 18 years of age and older.

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.

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The drug, Potiga (ezogabine), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist
- Must be age 18 years or older
- Must have diagnosis of partial-onset seizures
- Must have had an inadequate response or intolerance to at least 2 generic antiepileptic medications
- Must be using ezogabine (Potiga) as adjunctive therapy to other anti-epileptic drugs (AEDs)
- Must have a baseline ophthalmic exam prior to starting therapy with ezogabine (Potiga)

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 the following:

- Chart documentation from the provider that the member's condition has improved based upon the prescriber's assessment while on therapy
- Chart documentation to confirm that the member is monitored by an ophthalmic professional every 6 months
- Chart documentation to confirm that the member is being monitored for discoloration of nails, lips, and/or skin

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Potiga 50mg	270 tablets per 30 days
Potiga 200mg, 300mg	90 tablets per 30 days
Potiga 400mg	60 tablets per 30 days

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

REFERENCES

1. Potiga [package insert]. Research Triangle Park, NC: GlaxoSmithKline; June 2011.
2. Porter RJ, Patriot A, Sachdeo R, et al. Randomized, multicenter, dose-ranging trial of retigabine for partial-onset seizures. *Neurology*. 2007;68:1197-1204.
3. French JA, Abou-Khalil BW, Leroy RF, et al. Randomized, double-blind, placebo-controlled trial of ezogabine (retigabine) in partial epilepsy. *Neurology*. 2011;76:1-9
4. Brodie MJ, Lerche H, Gil-Nagel A, et al. Efficacy and safety of adjunctive ezogabine (retigabine) in refractory partial epilepsy. *Neurology*. 2010;75:1817-1824
5. U.S. Food and Drug Administration: FDA approves label changes for anti-seizure drug Potiga (ezogabine) describing risk of retinal abnormalities, potential vision loss, and skin discoloration. FDA Drug Safety Communication. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm372774.htm. Accessed November 21, 2013.

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	*02/17, 02/18*

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