Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Gralise (gabapentin ER)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2011 (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 Gralise (gabapentin ER).

Gralise (gabapentin ER) is indicated for the management of postherpetic neuralgia (PHN).

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, Gralise (gabapentin ER), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of Postherpetic Neuralgia
- Must have an adequate trial and failure of generic gabapentin defined as either of the following:
    - Failure due to insufficient efficacy at a dose of at least 1800mg per day.
    - Failure due to intolerance. Chart documentation showing slow titration of dose must be provided.
- Must have an adequate trial and failure of a tricyclic antidepressant, such as amitriptyline or nortriptyline, or a contraindication to these agents

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Level Limit	
Gralise 300mg	30 tablets per 30 days
Gralise 600mg	90 tablets per 30 days
Gralise starter pack	1 pack per lifetime

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

REFERENCES

1. Gralise [package insert]. North Chicago, IL: Abbott Laboratories; January 2011.
2. Wallace M, Irving G, Cowles V. Gabapentin Extended-Release Tablets for the Treatment of Patients with Postherpetic Neuralgia: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Stud. Clinical Drug Investigation 30;11:765-776.
3. Dubinsky RM, Kabbani H, El-Chami Z, Boutwell C, Ali H. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2004 Sep 28;63(6):959-65.

RECORD RETENTION

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*

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