

## STEP THERAPY POLICY

- POLICY:** Gabapentin Step Therapy Policy
- Gralise® (gabapentin extended release tablets – Depomed)
  - Horizant® (gabapentin enacarbil extended-release tablets – GlaxoSmithKline)
  - Neurontin® (gabapentin capsules and solution – Pfizer, generics)

**REVIEW DATE:** 07/29/2020

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### OVERVIEW

Gabapentin, Gralise, and Horizant are indicated for:<sup>1-3</sup>

- Management of postherpetic neuralgia in adults.
- Gabapentin is also approved as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and children  $\geq 3$  years of age with epilepsy.
- Horizant is also indicated for moderate-to-severe restless leg syndrome (RLS) in adults.

Gralise and gabapentin (Neurontin, generics) are analogs of the neurotransmitter gamma-aminobutyric acid (GABA).<sup>1,2</sup> Horizant is a prodrug of gabapentin.<sup>3</sup> These drugs exert their pharmacologic action by binding to the alpha-2-delta subunit of voltage-gated calcium channels.<sup>1-3</sup> The binding of this subunit reduces the release of several neurotransmitters including glutamate, noradrenaline, and substance P. Gabapentin is available as capsules and oral solution; Gralise and Horizant are available as extended-release (ER) tablets. Product labeling for Gralise and Horizant note that they are not to be used interchangeably with other gabapentin products due to differing pharmacokinetic profiles that affect frequency of administration or different plasma concentrations relative to other gabapentin products. Gralise and Horizant are dosed once daily and should be taken with evening meals, whereas gabapentin is dosed three times a day and can be taken without regard to food.

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 drug prior to the use of a Step 2 drug. If the Step Therapy rule is not met for a Step 2 drug at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** A patient with a history of one Step 1 drug within the 130-day look-back period is excluded from step therapy.

**Step 1:** gabapentin capsules, tablets, and oral solution

**Step 2:** Gralise, Horizant, Neurontin

### CRITERIA

1. If the patient has tried one Step 1 product (brand [Neurontin] or generic), authorization for a Step 2 product may be given.
2. No other exceptions are recommended.

**REFERENCES**

1. Neurontin<sup>®</sup> capsules, tablets, oral solution [prescribing information]. New York, NY: Pfizer, Inc.; April 2020.
2. Gralise<sup>®</sup> tablets [prescribing information]. Morristown, NJ: Almatica Pharma, Inc.; April 2020.
3. Horizant<sup>®</sup> extended-release tablets [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; April 2020.