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# 5.75.013

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Neuromuscular Drugs	<b>Original Policy Date:</b>	June 20, 2013
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**Last Review Date:** June 13, 2024

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## Gabapentin Powder

### Description

#### Gabapentin Powder

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#### Background

Gabapentin capsules, tablets, and oral solution are used to help control certain types of seizures in people who have epilepsy. Gabapentin capsules, tablets, and oral solution are also used to relieve the pain of post-herpetic neuralgia (PHN; the burning, stabbing pain or aches that may last for months or years after an attack of shingles). Gabapentin extended-release tablets (Horizant) are used to treat restless legs syndrome (RLS; a condition that causes discomfort in the legs and a strong urge to move the legs, especially at night and when sitting or lying down). Gabapentin is in a class of medications called anticonvulsants. Gabapentin treats seizures by decreasing abnormal excitement in the brain. Gabapentin relieves the pain of PHN by changing the way the body senses pain (1).

Gabapentin is commercially available as 100mg, 300mg, and 400mg capsules and tablets, 600mg and 800mg tablets, and a 250mg/5 ml solution (2).

#### Regulatory Status

Gabapentin is FDA-approved in an oral formulation for the management of postherpetic neuralgia in adults and also as an adjunctive therapy in the treatment of partial onset seizures with and without secondary generalization in patients 12 years of age with epilepsy, and as adjunctive therapy in the treatment of partial onset seizures in pediatric patients age 3 to 12 years. Gabapentin is also indicated for treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults (2-3).

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Gabapentin is recommended for add-on therapy in patients 3 years of age and older. Effectiveness in pediatric patients below the age of 3 years has not been established (2).

#### Off-Label Uses:

Off-label (non-FDA approved) compounded topical preparations of gabapentin have not been shown to be superior to commercially available topical diclofenac preparations.

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#### **Related policies**

Gabapentin

#### **Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Gabapentin may be considered **medically necessary** if the conditions indicated below are met.

Gabapentin may be considered **investigational** for all other indications.

## **Prior-Approval Requirements**

### **Diagnoses**

Patient must have **ONE** of the following:

1. Postherpetic neuralgia
  - a. 18 years of age or older
2. Partial seizure epilepsy
  - a. Ages 3 -12 years of age
  - b. Adjunctive therapy
3. Partial seizure epilepsy with or without secondary generalization
  - a. 12 years of age or older
  - b. Adjunctive therapy
4. Restless Legs Syndrome (RLS)

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- a. 18 years of age or older

**AND ALL** of the following:

- a. The requested dosage form is for oral use
- b. The requested dosage unit does not exceed the FDA approved dose of 800 mg/unit
- c. The requested dose is not commercially available

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## **Prior – Approval *Renewal* Requirements**

Same as above

### [Policy Guidelines](#)

## **Pre - PA Allowance**

None

## **Prior - Approval Limits**

**Duration** 12 months

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## **Prior – Approval *Renewal* Limits**

Same as above

### [Rationale](#)

#### **Summary**

Gabapentin is FDA-approved in an oral formulation for the management of post-herpetic neuralgia in adults, as an adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients 12 years of age with epilepsy and as adjunctive therapy in the treatment of partial seizures in pediatric patient's age 3 to 12 years. Gabapentin is also indicated for the treatment of Restless Legs Syndrome (RLS). There are no clinical studies to support the safety and effectiveness of gabapentin in a topical delivery system (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of gabapentin while maintaining optimal therapeutic outcomes.

#### **References**

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1. Medline Plus [Internet]. Bethesda (MD): National Library of Medicine (US); updated 2022 March 25; accessed 2022 April 12 available from:  
<http://www.medlineplus.gov/druginfo/meds/a694007.html>
2. Neurontin [package insert]. New York, New York: Pfizer; July 2022.
3. Horizant [package insert]. Wobum, MA: Azurity Pharmaceuticals, Inc.; August 2022.

## Policy History

Date	Action
June 2013	New addition to PA
September 2014	Annual criteria review and reference update
December 2015	Annual editorial review
December 2016	Annual editorial review and reference update Policy number change from 5.15.01 to 5.75.13
September 2017	Annual editorial review and reference update
June 2018	Annual editorial review and reference update
September 2019	Annual review and reference update
September 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual review and reference update
June 2023	Annual review. Changed policy number to 5.75.013
June 2024	Annual review and reference update

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.**