

5.75.017

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Neuromuscular Agents	<b>Original Policy Date:</b>	April 28, 2017
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**Last Review Date:** December 8, 2023

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## Gabapentin

### Description

#### Gabapentin (Gralise\*, Horizant\*, Neurontin)

\*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

#### Background

Gabapentin is used in the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), neuropathic pain associated with spinal cord injury, partial onset seizures, postherpetic neuralgia (PHN), or Restless Legs Syndrome (RLS). Gabapentin is thought to reduce the release of a neurotransmitter called glutamate. Glutamate is a neurotransmitter that acts as a natural 'nerve-exciting' agent. It is released when electrical signals build up in nerve cells and subsequently excites more nerve cells (1-3).

#### Regulatory Status

FDA-approved indications: (1-3)

1. **Gabapentin** is indicated for postherpetic neuralgia in adults, adjunctive therapy in the treatment of partial onset seizures with and without secondary generalization in adults and pediatric patients 3 years and older.
2. **Graslise** is indicated for the management of postherpetic neuralgia (PHN).
3. **Horizant** is indicated for the:
  - treatment of moderate-to-severe primary restless legs syndrome (RLS)
  - management of postherpetic neural (PHN) in adults

In clinical studies, gabapentin efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day (1-3).

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The safety and efficacy of gabapentin in the management of postherpetic neuralgia in pediatric patients have not been established. Effectiveness as adjunctive therapy in the treatment of partial seizures in pediatric patients below the age of 3 years has not been established (1).

**Related policies**

Gabapentin powder, Lyrica, Savella

**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**

**Age** 3 years of age or older

**Diagnosis**

Patient must have the following:

1. Partial onset seizures
  - a. Used in combination with other first line anti-epileptic medications
  - b. **NO** dual therapy with pregabalin (Lyrica)

**Age** 18 years of age or older

**Diagnoses**

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

1. Neuropathic pain
2. Post-herpetic neuralgia (PHN)
3. Restless legs syndrome (RLS)

**AND** the following:

- a. **NO** dual therapy with pregabalin (Lyrica)

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## Prior – Approval *Renewal* Requirements

Same as above

### Policy Guidelines

## Pre - PA Allowance

**Age** 3 years of age or older

**Quantity**

### Gabapentin

Strength	Quantity Limit
100mg, 300mg, 400mg, 600mg, 800mg	3600mg per day
50mg/mL solution	

## Prior - Approval Limits

**Quantity**

### Gabapentin

Strength	Quantity Limit
100mg, 300mg, 400mg, 600mg, 800mg	Pre-PA allows for the FDA recommended maximum dosage
50mg/mL solution	

Medication / Strength <u>with approved FE only</u>	Quantity Limit
Gralise 300mg, 450mg, 600mg, 750mg, 900mg	3600mg per day <b>OR</b>
Horizant 300mg, 600mg	3600mg per day

**Duration** 24 months

## Prior – Approval *Renewal* Limits

Same as above

### Rationale

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### Summary

Gabapentin is used in the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), neuropathic pain associated with spinal cord injury, partial onset seizures, postherpetic neuralgia (PHN), or restless legs syndrome (RLS). Gabapentin is thought to reduce the release of a neurotransmitter called glutamate. As gabapentin reduces the release of this neurotransmitter it can also be used to treat nerve pain that occurs as a result of damage to or a disturbance in the function of nerves (neuropathic pain) (1-3).

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

### References

1. Neurontin [package insert]. New York, NY: Pfizer Pharmaceuticals, Inc.; December 2020.
2. Horizant [package insert]. Atlanta, GA: Arbor Pharmaceuticals LLC; April 2020.
3. Gralise [package insert]. Morristown, NJ: Almatica Pharma LLC, Inc.; April 2023.

### Policy History

Date	Action
April 2017	Addition to PA
June 2017	Annual review
December 2017	Addition of the statement "Quantity limits listed above must be used to achieve dose optimization"
March 2018	Annual review
June 2018	Annual review and reference update. Removal of tapers from criteria. Addition of no dual therapy with pregabalin (Lyrica)
September 2019	Annual review and reference update
December 2019	Annual review. Moved Gralise and Horizant to MFE with PA only
September 2020	Annual review and reference update
December 2020	Annual review. Added statement to regulatory status per SME: "The extended-release formulations (Gralise and Horizant) may only be approved if the patient has failed at least one immediate-release formulation."
June 2021	Annual review
June 2022	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.75.017
February 2023	Revised quantity charts to remove specific quantities and set all dosage forms and strengths at 3600 mg per day
March 2023	Annual review

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May 2023	Added Gralise 450mg, 750mg and 900mg strengths to the policy
June 2023	Annual review
December 2023	Annual review

## Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.