BlueCross BlueShield
Federal Employee Program.
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.75.017

Section:	Prescription Drugs	**Effective Date:**	January 1, 2023
Subsection:	Neuromuscular Agents	**Original Policy Date:**	April 28, 2017
Subject:	Gabapentin	**Page:**	1 of 5

Last Review Date: December 2, 2022

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, 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's released when electrical signals build up in nerve cells and subsequently excites more nerve cells. 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).

Regulatory Status
FDA-approved indications: 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 and treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) (1-3).

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

The extended-release formulations (Gralise and Horizant) may only be approved if the patient has failed at least one immediate-release formulation.

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** in patients 3 years of age or older for the treatment of partial onset seizures and if the conditions indicated below are met.

Gabapentin may be considered **medically necessary** in patients 18 years of age or older for the treatment of neuropathic pain, postherpetic neuralgia, or restless legs syndrome (RLS) and if the conditions indicated below are met.

Gabapentin may be considered **investigational** in patients for all other indications and ages.

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. Postherpetic neuralgia
3. Restless legs syndrome (RLS)

AND the following:

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

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	540 dosage units per 90 days **OR**
800mg	360 dosage units per 90 days **OR**
50mg/mL solution	6480mL per 90 days

Maximum daily limit of any combination: 3600mg

Prior - Approval Limits

Quantity

Gabapentin

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

Medication / Strength with approved MFE only	Quantity Limit
Gralise 300 mg, 600 mg	540 dosage units per 90 days

Horizant 300 mg, 600 mg	540 dosage units per 90 days

Duration 24 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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, 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]. Newark, CA: Depomed, Inc.; April 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2022 and is effective on January 1, 2023.