Effective Date **9/1/2024**
Coverage Policy Number **IP0317**

Gabapentin Extended-Release

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions for the following gabapentin products:

- **Gralise**® (450 mg, 750 mg, 900 mg gabapentin extended-release tablets)
- **Gralise**® **30-Day Starter Pack** (gabapentin extended-release tablets)
- **Horizant**® (gabapentin enacarbil extended-release tablets)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
Gralise	The patient has tried ONE of the following:

Non-Covered Product	Criteria
(450 mg, 750 mg, 900 mg gabapentin extended-release tablets)	1. Gabapentin capsules / tablets 2. Pregabalin capsules 3. Pregabalin ER
Gralise 30-Day Starter Pack (gabapentin extended-release tablets)	The patient has tried ONE of the following: 1. Gabapentin capsules / tablets 2. Pregabalin capsules 3. Pregabalin ER
Horizant (gabapentin enacarbil extended-release tablets)	The patient has tried ONE of the following: 1. Gabapentin capsules / tablets 2. Pregabalin capsules 3. Pregabalin ER

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of gabapentin products are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
Gabapentin, Gralise, and Horizant are indicated for the following uses:[1-3]

- 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 ≥ 3 years of age with epilepsy.
- Horizant is also indicated for moderate-to-severe **restless leg syndrome** (RLS) in adults.

Gralise and gabapentin (Neurontin, generic) are analogs of the neurotransmitter gamma-aminobutyric acid (GABA).[1,2] Horizant is a prodrug of gabapentin.[3] These drugs exert their pharmacologic action by binding to the alpha-2-delta subunit of voltage-gated calcium channels.[1-3] 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 different 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.

References

1. Neurontin® capsules, tablets, oral solution [prescribing information]. New York, NY: Pfizer; December 2020.
2. Gralise tablets [prescribing information]. Morristown, NJ: Almatica; April 2023.
3. Horizant extended-release tablets [prescribing information]. Atlanta, GA: Arbor; April 2020.