Pharmacy Medical Necessity Guidelines: Gabapentin Medications (Gralise®, Horizant®)

Effective: October 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Gralise® (gabapentin extended-release) is indicated for the management of postherpetic neuralgia (PHN).

Horizant® (gabapentin enacarbil) is indicated for the treatment of moderate-to-severe restless leg syndrome and for the management of PHN in adults.

There is a risk of serious breathing difficulties that can lead to death in patients who use gabapentinoids with opioid pain medicines or other drugs that depress the central nervous system, or those who have underlying respiratory impairment, such as patients with chronic obstructive pulmonary disease or the elderly.

COVERAGE GUIDELINES

The plan may authorize coverage of non-preferred gabapentin products (Horizant®, Gralise®) for Members when **ALL** of the following criteria for a particular regimen are met and limitations do not:

Gralise® (gabapentin extended-release)

1. The Member is diagnosed with postherpetic neuralgia

AND

2. The Member had an inadequate response, intolerance, or contraindication to ONE of the following: immediate-release gabapentin or pregabalin

AND

3. The Member had an inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant

Horizant® (gabapentin enacarbil extended-release)

1. The Member meets ALL of the following:
   a. The Member is diagnosed with restless leg syndrome

   AND

   b. The Member had an inadequate response, intolerance, or contraindication to immediate-release gabapentin

OR

2. The Member meets ALL of the following:
   a. The Member is diagnosed with postherpetic neuralgia

   AND

   b. The Member had an inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant

   AND

   c. The member had an inadequate response, adverse reaction, or contraindication to ONE of the following: immediate-release gabapentin or pregabalin

LIMITATIONS

1. The quantity is limited to three tablets per day (300 mg, 450 mg, 600 mg) or two tablets per day (750 mg, 900 mg) for Gralise® and two tablets per day for Horizant®.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Food and Drug Administration. FDA in Brief: FDA requires new warnings for gabapentinoids about risk of respiratory depression. Available from: https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-new-warnings-gabapentinoids-about-risk-respiratory-depression. Accessed 27 December 2019.
2. Gralise (gabapentin tablets) [prescribing information]. Morristown, NJ: Almatica Pharma LLC; July 2024.
3. Horizant (gabapentin enacarbil extended-release tablets) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; August 2023.
4. Neurontin (gabapentin) [prescribing information]. New York, NY: Pfizer; July 2022.
5. Ortega E. Postherpetic neuralgia. UpToDate. Available at: www.uptodate.com. Accessed 4 August 2023.
6. Silber MH. Management of restless legs syndrome and periodic limb movement disorder in adults. UpToDate. Available at: www.uptodate.com. Accessed 4 August 2023.
7. Silber MH, Buchfuhrer MJ, Earley CJ, et al. The management of restless legs syndrome: an updated algorithm. *Mayo Clin Proc.* 2021;96(7):1921-1937.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective October 1, 2023, updated criteria to include pregabalin as a previous trial option for postherpetic neuralgia.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: Effective October 1, 2026, updated Limitations section to clarify different quantity limits for Gralise based on strength and added following statement due to generic availability of Gralise, "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria".

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.