

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

Effective: January 12, 2021

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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p>Fax Numbers: RXUM: 617.673.0988</p>	

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). Gralise® is available in 300 mg and 600 mg tablets and can be titrated up to 1800 mg once daily. Gralise® should be administered with the evening meal.

Horizant® (gabapentin encarbil) is indicated for the treatment of moderate-to-severe restless leg syndrome and for the management of PHN in adults. Horizant® is available in 300 mg and 600 mg tablets. The dose for restless leg syndrome is 600 mg once daily taken at 5 PM; a dose of 1,200 mg once daily provided no additional benefit compared with the 600-mg dose but it caused an increase in adverse reactions. The starting dose for the treatment of PHN is 600 mg in the morning for three days, then increase to 600 mg twice daily beginning on day 4. A daily dose greater than 1,200 mg/day provided no additional benefit.

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)

- The Member is diagnosed with postherpetic neuralgia made by a neurologist
- AND**
- The Member had an inadequate response or adverse reason to immediate-release gabapentin
- AND**
- The Member had an inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant

Horizant® (gabapentin encarbil extended-release)

- The Member is diagnosed with restless leg syndrome
- AND**
- A course of therapy with immediate-release gabapentin did not provide sustained relief throughout the night

AND

3. The Member failed a course of therapy with at least two dopamine agonist agents, or the Member has a contraindication to therapy with at least two dopamine agonist agents (e.g., pramipexole, ropinirole, levodopa, or cabergoline)

AND

4. If the member is taking Horizant in conjunction with opioids or has underlying respiratory impairment: The risk of breathing difficulties has been discussed with the member

OR

1. The Member is diagnosed with postherpetic neuralgia made by a neurologist

AND

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

AND

3. The member had an inadequate response or adverse reaction to immediate-release gabapentin

Reauthorization of Gralise and Horizant

1. The Member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary.

LIMITATIONS

1. Approval duration for Gralise® and Horizant® is limited to one year.
2. The quantity is limited to three tablets per day for Gralise® and two tablets per day for Horizant®.

CODES

None

REFERENCES

1. Gralise (gabapentin tablets) [prescribing information]. Morristown, NJ: Almatica Pharma LLC; April 2020.
2. Horizant (gabapentin enacarbil extended-release tablets) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; April 2020.
3. Food and Drug Administration. FDA in Brief: FDA requires new warnings for gabapentinoids about risk of respiratory depression. Available from: [fda.gov/news-events/fda-brief/fda-brief-fda-requires-new-warnings-gabapentinoids-about-risk-respiratory-depression](https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-new-warnings-gabapentinoids-about-risk-respiratory-depression). Accessed 27 December 2019.
4. Neurontin (gabapentin) [prescribing information]. New York, NY: Pfizer; October 2017.

APPROVAL HISTORY

July 19, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 4, 2014: No changes
2. November 10, 2015: No changes
3. January 1, 2016: Administrative change to rebranded template.
4. September 13, 2016: Added PBHMI criteria for gabapentin immediate release.
5. January 10, 2016: Applied PBHMI criteria to Gralise® and Horizant®
6. February 14, 2017: Administrative update to change the length of approval for gabapentin immediate release to life time approval.
7. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed PBHMI criteria. May 8, 2018: Separated criteria for Horizant® and Gralise® such that Gralise® will only be approved for postherpetic neuralgia. For the diagnosis of postherpetic neuralgia, added the requirement that there must be trial and failure of a tricyclic antidepressant.
8. March 12, 2019: Administrative update, removed length of approval for gabapentin immediate-release from the limitations section. Administrative changes made to template.
9. January 14, 2020: No changes.
10. January 12, 2021: No changes.

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.