Pharmacy Medical Necessity Guidelines: Gabapentin Medications (Gralise®, Horizant®, gabapentin immediate-release)

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

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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 enacarbil extended-release) 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 less 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.

The Pediatric Behavioral Health Medication Initiative (PBHMI) has been implemented to encourage safe prescribing of behavioral health medication regimens in Members less than 18 years of age. As part of the PBHMI, a prior authorization is required for pediatric Members less than 6 years of age prescribed gabapentin immediate release.

COVERAGE GUIDELINES

The plan may authorize coverage of a gabapentin-containing medication (gabapentin immediate release, Gralise® and Horizant®) for members less than 6 years of age when the following criteria are met:

1. Member meets **one** of the following:

    a. Recent psychiatric hospitalization (within the last three months)

    OR

    b. History of severe risk of harm to self or others

    OR

    c. Seizure diagnosis only

    OR

    Member has **all** of the following:

    a. An appropriate diagnosis

    AND

b. Treatment plan including the names of current behavioral health medications and corresponding indications

AND

c. Prescriber is a specialist (e.g., neurologist, psychiatrist), or a consult is provided

Gralise® and Horizant® Medication-Specific Criteria

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 apply (age-specific criteria must be met in addition to the medication-specific criteria listed below):

Gralise® (gabapentin extended-release)

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

AND

2. The Member had an inadequate response or adverse reason to immediate-release gabapentin

AND

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

Horizant® (gabapentin encarbil)

1. The Member is diagnosed with restless leg syndrome

AND

2. 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)

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. Approval duration for gabapentin immediate release is life of plan.
3. The quantity is limited to three tablets per day for Gralise® and two tablets per day for Horizant®
4. Requests for gabapentin medications in which the Pediatric Behavioral Health Medication Initiative (PBHMI) polypharmacy limits are exceeded will also be reviewed against the PBHMI polypharmacy criteria.

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. 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, Adding Tufts Health RITogether to the template.
8. 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.
9. March 12, 2019: Administrative changes made to template.
10. January 14, 2020: Administrative update, added to the limitations section that requests for members who exceed the PBHMI polypharmacy limits will be reviewed against the PBHMI polypharmacy criteria.
11. 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.