# Select Gabapentin Products

**Policy #** 00515
Original Effective Date: 01/01/2017
Current Effective Date: 06/10/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

# When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider branded gabapentin products, including, but not limited to Gralise®‡, Horizant®‡, Neurontin®‡, and gabapentin extended release tablets to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Gralise, gabapentin extended release tablets, Horizant, or Neurontin when the criteria are met for the requested drug:

- For Gralise 300 mg or 600 mg tablet requests:
    - There is clinical evidence or patient history that suggests the use of generically available immediate release oral gabapentin will be/was ineffective or will/did cause an adverse reaction to the patient; AND
    - There is clinical evidence or patient history that suggests the use of the generically available extended release gabapentin tablets will be/was ineffective or will/did cause an adverse reaction to the patient.
- For Gralise 450mg, 750mg, or 900mg tablet, gabapentin extended release tablet, or Neurontin requests:
    - There is clinical evidence or patient history that suggests the use of generically available oral gabapentin immediate release will be/was ineffective or will/did cause an adverse reaction to the patient.

- For Horizant requests:
  - If diagnosis is post herpetic neuralgia: There is clinical evidence or patient history that suggests the use of generically available oral gabapentin will be/was ineffective or will/did cause an adverse reaction to the patient; OR
  - If diagnosis is restless leg syndrome: There is clinical evidence or patient history that suggests the use of generically available oral pramipexole or generically available oral ropinirole will be/was ineffective or will/did cause an adverse reaction to the patient.

# When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of branded gabapentin products, including, but not limited to Gralise, Horizant, Neurontin, or gabapentin extended release tablets WITHOUT clinical evidence or patient history that suggests the use of the preferred generic products mentioned in the patient selection criteria for each requested drug and/or indication will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

# Background/Overview

Gralise carries an indication for the treatment of post herpetic neuralgia. Horizant (which is a different salt of gabapentin) is indicated for the treatment of post herpetic neuralgia as well as restless leg syndrome. Neurontin and generic gabapentin carry indications for post herpetic neuralgia and seizures. Pramipexole and ropinirole are generically available agents that are commonly used to treat restless leg syndrome. All of the branded gabapentin products mentioned in this policy were compared head to head with placebo in clinical trials, therefore no claims of superiority can be made for any of these branded products over the generic alternatives. Given the overlap in indications of these products, coupled with the generic availability of gabapentin, pramipexole, and ropinirole, utilization of these alternative generic products is a clinically and economically sensible option.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

Horizant was approved in April of 2011 for the treatment of moderate to severe restless leg syndrome in adults and for the management of post herpetic neuralgia in adults. Gralise was approved in January of 2011 for the treatment of post herpetic neuralgia, and select strengths of generic versions

of gabapentin extended release tablets became available in February of 2024. Neurontin was approved in 1993 for the treatment of post herpetic neuralgia in adults as well as for the adjunctive treatment of partial onset seizures. There are generic versions of Neurontin available on the market. Requip®‡ (ropinirole) was approved in 1997, and Mirapex®‡ (pramipexole) was approved in 1997. Both Mirapex and Requip are approved for the treatment of Parkinson's disease and for moderate to severe restless leg syndrome. The extended release versions are approved for Parkinson's disease only. Both products are available in generic formulations.

# Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of the preferred generic products mentioned in the patient selection criteria for each requested drug and/or indication will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using branded gabapentin products, including, but not limited to Gralise, Horizant, or Neurontin over the preferred generic products mentioned in the patient selection criteria for each requested drug and/or indication mentioned in this policy.

# References

1. Horizant [package insert]. Xenoprot, Inc. Santa Clara, California. Updated July 2013.
2. Gralise [package insert]. Depomed. Newark, California. Updated April 2023.
3. Neurontin [package insert]. Pfizer. New York, New York. Updated September 2015.
4. Requip [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated August 2014.
5. Mirapex [package insert]. Boehringer Ingelheim. Ridgefield, Connecticut. Updated January 2016.
6. Gabapentin extended release tablet [package insert]. Various manufacturers. Updated January 2024.

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# Policy History

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| 08/04/2016 | Medical Policy Committee review |
| 08/17/2016 | Medical Policy Implementation Committee approval. New Policy. |
| 08/03/2017 | Medical Policy Committee review |
| 08/23/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/09/2018 | Medical Policy Committee review |
| 08/15/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/01/2019 | Medical Policy Committee review |
| 08/14/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/06/2020 | Medical Policy Committee review |
| 08/12/2020 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/05/2021 | Medical Policy Committee review |
| 08/11/2021 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/04/2022 | Medical Policy Committee review |
| 08/10/2022 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/03/2023 | Medical Policy Committee review |
| 08/09/2023 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 05/02/2024 | Medical Policy Committee review |
| 05/08/2024 | Medical Policy Implementation Committee approval. Added new generic, gabapentin extended release tablet, to the policy and Gralise strengths to distinguish products. Added criteria for Gralise 300mg and 600 mg tablets to include trial and fail of the generic product. Title changed from “Branded Gabapentin Products” to “Select Gabapentin Products”. |

Next Scheduled Review Date: 05/2025

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**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.