STEP THERAPY POLICY

POLICY: Gabapentin Step Therapy Policy
- Gralise® (gabapentin extended release tablets – Almatica, generic)
- Horizant® (gabapentin enacarbil extended-release tablets – Arbor)
- Neurontin® (gabapentin capsules, tablets, and solution – Pfizer, generic)

REVIEW DATE: 02/07/2024

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Gabapentin, gabapentin ER (Gralise, generic), 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.

Gabapentin ER (Gralise, generic) 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, tablets, and oral solution; gabapentin ER and Horizant are available as extended-release (ER) tablets. Product labeling for gabapentin ER 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. Gabapentin ER 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.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Gabapentin product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

Step 1: generic gabapentin capsules, tablets, and oral solution

Step 2: Gralise (brand and generic), Horizant, Neurontin

CRITERIA

1. If the patient has tried one Step 1 Product (brand [Neurontin] or generic), approve a Step 2 Product.

REFERENCES

1. Neurontin® capsules, tablets, oral solution [prescribing information]. New York, NY: Pfizer; July 2022.
2. Gralise® tablets [prescribing information]. Morristown, NJ: Almatica; April 2023.
3. Horizant® extended-release tablets [prescribing information]. Atlanta, GA: Arbor; August 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/03/2022
Annual Revision	No criteria changes.	08/09/2023
Early Annual Revision	**Gabapentin ER tablets (generic for Gralise):** Added to step 2.	02/07/2024