MEDICAL MUTUAL®

Drug Policy

Policy:	**Gabapentin Step Therapy Policy**	**Annual Review Date:** **04/20/2023**
Impacted Drugs:	**Gralise (gabapentin)** **Horizant (gabapentin enacarbil)** **Pregabalin** **Pregabalin ER**	**Last Revised Date:** **04/20/2023**

OVERVIEW

Gabapentin is an analog of the neurotransmitter gamma-aminobutyric acid (GABA). Horizant is a prodrug of gabapentin. These drugs exert their pharmacologic action by binding to the alpha-2-delta subunit of voltage-gated calcium channels. The binding of this subunit reduces the release of several neurotransmitters including glutamate, noradrenaline, and substance P. It has been postulated that Lyrica has a stronger receptor affinity and, therefore, may be more potent than any of the gabapentin products. The clinical relevance of this has yet to be established.

Despite their pharmacologic similarities, Lyrica and the gabapentin products do differ in some respects. For example, Lyrica can be dosed twice daily (BID) or three times daily (TID) whereas gabapentin is dosed TID and Gralise and Horizant are dosed once daily (QD).

Lyrica is indicated for the management of postherpetic neuralgia (PHN), as adjunctive therapy in the treatment of partial onset seizures in adults, for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN), for the management of fibromyalgia, and for treatment of neuropathic pain associated with spinal cord injury. Gabapentin and Gralise are indicated for the management of PHN. Gabapentin is also approved as adjunctive therapy in the treatment of partial onset seizures in adults and children. Horizant is indicated for moderate-to-severe restless leg syndrome (RLS) in adults and PHN.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 or step 3 medication. If the step therapy rule is not met for a Step 2 medication at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 medication within the 130-day look-back period are excluded from step therapy for Step 2 requests. Patients with a history of one step 2 medications within the 130-day look-back period are excluded from step therapy for step 3 requests.

Step 1 medication
- Generic gabapentin capsules, tablets, and oral solution

Step 2 medication
- Pregabalin

Step 3 medication
- Gralise
- Pregabalin ER
- Horizant

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried one step 1 medication, then authorization for step 2 medication may be given.
2. If the patient has tried one step 1 medication and one step 2 medication, then authorization for a step 3 medication may be given.
3. Exceptions may be made for pregabalin if the patient is established on therapy for a neuropathic pain condition (e.g., fibromyalgia, postherpetic neuralgia, and diabetes and spinal cord related neuropathic pain).
4. Exceptions may be made for pregabalin if the patient has a seizure disorder and is currently stable on the medication.
5. Exceptions may be made for generic pregabalin if it is being prescribed for the treatment of general anxiety disorder (GAD) if the patient has tried at least two of the following: buspirone, a tricyclic antidepressant (TCA) such as imipramine and nortriptyline, a selective serotonin reuptake inhibitor (SSRI) such as paroxetine and Lexapro. Note: The two agents tried do not have to be from different classes. For example, an exception should be made for a patient who has tried two SSRIs.
6. Exceptions may be made for generic pregabalin for restless leg syndrome for an adult.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**

C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Guay DRP. Pregabalin in neuropathic pain: a more "pharmaceutically elegant" gabapentin? *Am J Geriatr Pharmacother*. 2005;3:274-287.
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4. Neurontin® capsules, tablets, oral solution [prescribing information]. New York, NY: Pfizer, Inc.; April 2015.
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6. Imamura S. and Kishida C. Gabapentin enacarbil (XP13512/GSK1838262) as an alternative treatment to dopaminergic agents for restless legs syndrome. *Expert Opin Phermacother*. 2010;11(11):1925-1932.

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8. Gabapentin. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 8 April 2019. Accessed on 22 April 2019.