Pharmacy Medical Necessity Guidelines:
Pregabalin (Lyrica) and Pregabalin extended-release (Lyrica CR)

Effective: September 9, 2025

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Pregabalin (Lyrica) is indicated for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- Management of postherpetic neuralgia
- Adjunctive therapy for the treatment of partial onset seizures in patients 1 month of age and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

Pregabalin extended-release (Lyrica CR) is indicated for:

- Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- Postherpetic neuralgia

Efficacy of pregabalin extended-release has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.

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

Initial Criteria

Pregabalin (Lyrica)

The plan may authorize coverage of pregabalin (Lyrica) for Members when **ALL** the following criteria for a particular condition are met and limitations do not apply:

1. The Member meets one of the following conditions:
    a. The Member has a diagnosis of fibromyalgia

    AND

    b. The Member had an inadequate response, adverse reaction, or contraindication to at least two medications from different therapeutic classes: serotonin-norepinephrine reuptake inhibitor (SNRI), a selective serotonin receptor inhibitor (SSRI), a tricyclic antidepressant (TCA), or an anticonvulsant

    OR

    a. The Member has a diagnosis of partial-onset seizures

    AND

    b. The Member had an inadequate response, adverse reaction, or contraindication to at least two alternative anticonvulsant medications

    OR

    a. The Member has a diagnosis of pain (e.g. postherpetic neuralgia, diabetic peripheral neuropathy, neuropathic pain associated with spinal cord injury)

    AND

    b. The Member had an inadequate response, adverse reaction, or contraindication to one of the following: an antidepressant, an anticonvulsant (e.g., gabapentin), lidocaine patch

Pregabalin extended-release (Lyrica CR)

The plan may authorize coverage of pregabalin extended-release (Lyrica CR) for Members when **ALL** of the following criteria are met and limitations do not apply:

1. The Member has ONE of the following diagnoses:
    a. Postherpetic neuralgia
    b. Diabetic peripheral neuropathy

AND

2. The Member had an inadequate response, adverse reaction, or contraindication to ALL of the following:
    a. Gabapentin
    b. Pregabalin immediate release
    c. ONE of the following other treatment options: an antidepressant, an anticonvulsant, or lidocaine patch

Reauthorization Criteria (non-seizure diagnoses)

1. Documentation the Member's diagnosis has improved with pregabalin treatment

LIMITATIONS

1. The coverage of pregabalin immediate release (Lyrica) is limited to 3 capsules per day or 30 ml per day.
2. The coverage of pregabalin extended-release (Lyrica CR) is limited to 1 capsule per day.
3. Requests for seizure diagnosis will be approved for life of plan.
4. Requests for non-seizure diagnoses will be approved for 1 year.
5. Requests for brand-name products, with AB-rated generics, will also be reviewed according to the Brand name criteria.

CODES

None

REFERENCES

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APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, updated the reauthorization criteria to require documentation that the Member's condition has improved with pregabalin. Updated previous trial

language throughout guideline to "inadequate response, intolerance, or contraindication to." Updated pregabalin IR criteria for pain diagnosis to require step through with one agent instead of two.

2. September 10, 2024: Updated overview and criteria for Pregabalin (Lyrica) based on expanded age for treatment of partial onset seizures. Administrative fax number update.
3. September 9, 2025: 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.

Provider Services