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

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

Pregabalin (Lyrica) is indicated for:
- Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- Management of postherpetic neuralgia
- Adjunctive therapy for adult patients with partial onset seizures
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

Pregabalin extended-release (Lyrica) is indicated for:

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

Lyrica CR should be administered once daily after an evening meal. It should be swallowed whole and should not be split, crushed, or chewed. Efficacy of Lyrica CR 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

Lyrica (pregabalin)

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 tried and failed therapy with, or the Member has a contraindication to, at least two medications from different therapeutic class: duloxetine, 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 tried and failed therapy with, or the Member has a 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 tried and failed therapy with, or the Member has a contraindication to gabapentin and at least one other treatment option: an antidepressant, an anticonvulsant, lidocaine patch

Lyrica CR (pregabalin extended-release)

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. If the Member is less than 6 years of age, the age-specific criteria for members less than 6 years of age must be met before applying the medication-specific criteria listed below:

1. The Member has a diagnosis of either postherpetic neuralgia or diabetic peripheral neuropathy

AND

2. The Member tried and failed therapy with, has a contraindication to, or clinical inappropriateness of treatment with all of the following:

a) Gabapentin
b) Lyrica immediate release
c) One of the following other treatment options: an antidepressant, an anticonvulsant, or lidocaine patch

LIMITATIONS

1. The coverage of Lyrica (pregabalin immediate release) is limited to 3 capsules per day or 30 ml per day.
2. The coverage of Lyrica CR (pregabalin extended-release) 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; subsequent approval will require the Member had an office visit and was re-assessed for this condition within the past year.
5. Requests for brand-name products, with AB-rated generics, will also be reviewed according to the Brand name criteria.

CODES

None

REFERENCES

1. Lyrica (pregabalin) [prescribing Information] New York, NY; Pfizer Inc.; June 2020.
2. Lyrica CR (pregabalin extended-release) [prescribing information]. New York, NY; Pfizer; June 2020.
3. Blommel ML, Blommel AL. Pregabalin: an antiepileptic agent useful for neuropathic pain. *Am J Health Syst Pharm*. 2007;64(14):1475-1482.
4. Marcus D. Treatment of Nonmalignant Chronic Pain. Am Fam Physician 2000 Vol. 61:1331-8, 1345-6Bril V, England J, Franklin GM, et al, "Evidence-Based Guideline: Treatment of Painful Diabetic Neuropathy: Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation," *Neurology*, 2011, 76(20):1758-65.
5. Lyseng-Williamson KA, Siddiqui MA. Pregabalin: a review of its use in fibromyalgia. *Drugs*. 2008;68(15):2205-2223
6. 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.

APPROVAL HISTORY

June 4, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 9, 2015: Approval duration modified to 1 year.
2. January 1, 2016: Administrative change to rebranded template.
3. September 13, 2016: Added age-limit criteria for Members less than 6 years of age.
4. February 14, 2017: Removed "quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria" from the Medical Necessity Guideline.

5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed Pediatric Behavioral Health Medication Initiative (PBHMI) criteria. Updated criteria for the treatment of fibromyalgia.
6. February 13, 2018: Added criteria and quantity limit for Lyrica CR.
7. February 12, 2019: Administrative changes made to template. Updated length of approval for seizure diagnosis to life of plan. Added neuropathic pain associated with spinal cord injury as an example of an approvable pain diagnosis. For non-seizure diagnoses, renewal criteria were updated to require reassessment within the past year.
8. January 14, 2020: Administrative update, updated the limitations section to indicate that requests for brand-name products with AB-rated generics will also be reviewed against the Brand Name criteria.
9. January 12, 2021: Administrative update, updated the quantity limit for pregabalin capsules in the limitations section of the MNG.

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.