MEDICAL MUTUAL®

Drug Policy

Policy:	**Lyrica® CR (pregabalin extended-release tablets) Prior Approval**	**Annual Review Date: 07/21/2022** **Last Revised Date: 07/21/2022**

OVERVIEW

Lyrica CR is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). The efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures. Lyrica CR is an analog of the neurotransmitter gamma-aminobutyric acid (GABA). Lyrica CR is dosed once daily (QD), and it is a Schedule V controlled substance.

POLICY STATEMENT

This policy involves the use of Lyrica CR. Prior authorization is recommended for pharmacy benefit coverage of Lyrica CR. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lyrica CR is recommended in those who meet the following criteria:

1. **Neuropathic Pain Associated with Diabetic Peripheral Neuropathy (DPN).** Approve pregabalin extended-release tablets if the patient meets the following criteria:
   - **A)** Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic IR pregabalin; AND
   - **B)** If brand Lyrica CR is requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic pregabalin extended-release tablets; AND
     - **ii.** Patient cannot continue to use the generic due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

2. **Postherpetic Neuralgia.** Approve pregabalin extended-release tablets if the patient meets the following criteria:
   - **A)** Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic IR pregabalin; AND

B) If brand Lyrica CR is requested, the patient meets both of the following (i and ii):
- **i.** Patient has tried generic pregabalin extended-release tablets; AND
- **ii.** Patient cannot continue to use the generic due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Pregabalin extended-release tablets has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Fibromyalgia.** A double-blind, placebo-controlled, randomized withdrawal trial of pregabalin extended-release tablets in adults with fibromyalgia failed to demonstrate efficacy.

2. **Partial Onset Seizures.** A double-blind, placebo-controlled, randomized trial of pregabalin extended-release tablets as adjunctive therapy in adults with partial onset seizures failed to demonstrate efficacy.[1]

3. **Restless Legs Syndrome.** No data are available for pregabalin extended-release tablets for the treatment of restless legs at this time.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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

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