

## PRIOR AUTHORIZATION POLICY

**POLICY:** Lyrica CR Prior Authorization Policy

- Lyrica® CR (pregabalin extended-release tablets – Pfizer)

**REVIEW DATE:** 03/03/2021

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### OVERVIEW

Lyrica CR, an analog of gamma-aminobutyric acid (GABA), is indicated for the management of:<sup>1</sup>

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

The efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adults with partial onset seizures.<sup>1</sup>

Gabapentin immediate-release (IR), an analog of GABA, is indicated for the following uses:<sup>2</sup>

- **PHN**, management in adults.
- **Partial onset seizures**, with and without secondary generalization, as adjunctive therapy in adults and pediatric patients  $\geq 3$  years of age with epilepsy.

Pregabalin IR capsules and oral solution are indicated for the management of:<sup>3</sup>

- **Neuropathic pain associated with DPN.**
- **PHN.**
- **Partial onset seizures**, as adjunctive therapy for the treatment in patients  $\geq 1$  month of age.
- **Fibromyalgia.**
- **Neuropathic pain associated with spinal cord injury.**

### Disease Overview

PHN is the persistence of the pain of herpes zoster  $> 3$  months after resolution of the rash; it is relatively common, affecting 10% to 15% of those with herpes zoster.<sup>4</sup> Administration of antiviral agents within 72 hours of the onset of herpes zoster can reduce the intensity and duration of acute illness and can prevent PHN. Efforts to prevent herpes zoster and PHN are important in that 40% to 50% of patients with PHN do not respond to any treatment.

The diabetic neuropathies are a heterogeneous group of disorders with diverse clinical manifestations.<sup>5</sup> The early recognition and appropriate management of neuropathy in the patient with diabetes is important. Up to 50% of diabetic peripheral neuropathy (DPN) may be asymptomatic. Painful diabetic neuropathy affects 16% of patients with diabetes, and it is frequently unreported (12.5%) and more frequently untreated (39%).<sup>6</sup> If not recognized and if preventive foot care is not implemented, patients are at risk for injuries to their insensate feet.<sup>5</sup> Recognition and treatment of autonomic neuropathy may improve symptoms, reduce sequelae, and improve quality of life. Therapeutic strategies (pharmacologic and nonpharmacologic) for the relief of painful DPN can potentially reduce pain and improve quality of life.

### **Guidelines**

Various guidelines for the treatment of DPN, neuropathic pain, PHN, and restless legs syndrome recommend gabapentin or pregabalin immediate-release as treatment options.<sup>4-11</sup> Guidelines have not been updated to address Lyrica CR.

### **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Lyrica CR. All approvals are provided for the duration noted below.

**Automation:** None.

### **RECOMMENDED AUTHORIZATION CRITERIA**

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

#### **FDA-Approved Indications**

- 1. Neuropathic Pain Associated with Diabetic Peripheral Neuropathy (DPN).** Approve Lyrica CR for 1 year if the patient meets ONE of the following criteria (A or B):
  - A) Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic pregabalin; OR
  - B) Patient is currently established on therapy with Lyrica CR.
- 2. Postherpetic Neuralgia.** Approve Lyrica CR for 1 year if the patient meets ONE of the following criteria (A or B):
  - A) Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic pregabalin; OR
  - B) Patient is currently established on therapy with Lyrica CR.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Lyrica CR is not recommended in the following situations:

- 1. Fibromyalgia.** A double-blind, placebo-controlled, randomized withdrawal trial of Lyrica CR in adults with fibromyalgia failed to demonstrate efficacy.<sup>1</sup>
- 2. Partial Onset Seizures.** A double-blind, placebo-controlled, randomized trial of Lyrica CR as adjunctive therapy in adults with partial onset seizures failed to demonstrate efficacy.<sup>1</sup>
- 3. Restless Legs Syndrome.** No data are available for Lyrica CR 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.

## REFERENCES

1. Lyrica<sup>®</sup> CR extended-release tablets [prescribing information]. New York, NY: Pfizer, Inc.; April 2020.
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4. Dubinsky RM, Kabbani H, El-Chami Z, et al. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2004;63(6):959-965.
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9. Winkelman JW, Armstrong MJ, Allen RP, et al. Practice guideline summary: treatment of restless legs syndrome in adults. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2016;87:1-9.
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