Lyrica CR® (pregabalin)

Policy # 00617
Original Effective Date: 05/16/2018
Current Effective Date: 05/16/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Postherpetic Neuralgia
Based on review of available data, the Company may consider Lyrica CR®‡ (pregabalin) for the treatment of postherpetic neuralgia (PHN) to be **eligible for coverage** when the patient selection criteria are met**.**

Patient Selection Criteria
Coverage eligibility for Lyrica CR (pregabalin) will be considered when the following criteria are met:

- The patient has a diagnosis of PHN; AND
- The patient has tried and failed (e.g. intolerance or inadequate response) TWO of the following drugs for at least one month each: generic gabapentin, generic topical lidocaine patch, or generic amitriptyline unless there is clinical evidence or patient history that suggests the use of the alternative agents will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Diabetic Peripheral Neuropathy
Based on review of available data, the Company may consider Lyrica CR (pregabalin) for the treatment of diabetic peripheral neuropathy (DPN) to be **eligible for coverage** when the patient selection criteria are met**.**

Patient Selection Criteria
Coverage eligibility for Lyrica CR (pregabalin) will be considered when the following criteria are met:

- The patient has a diagnosis of DPN; AND
- The patient has tried and failed (e.g. intolerance or inadequate response) TWO of the following drugs for at least one month each: generic gabapentin, generic valproic acid, generic amitriptyline, generic venlafaxine, or generic duloxetine unless there is clinical evidence or patient history that suggests the use of the alternatives will be ineffective or cause an adverse reaction to the patient
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Lyrica CR (pregabalin) when the patient has not tried and failed at least TWO alternative treatment options for the requested indication for at least one month each to be **not medically necessary.****

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Lyrica CR (pregabalin) for indications other than PHN or DPN to be **investigational.***

Background/Overview

Lyrica CR is a controlled release formulation of pregabalin which is also available in an immediate release formulation. Both formulations of pregabalin work to decrease nerve pain by binding to a protein in central nervous system tissues. Lyrica CR is only indicated for the management of PHN and DPN and should be administered once daily after an evening meal. Because it is a controlled release formulation, Lyrica CR should be swallowed whole (not split, crushed, or chewed). The initial dose is 165 mg once daily which should be increased to 330 mg once daily within 1 week based on individual patient response and tolerability. If the patient does not respond after 2-4 weeks of treatment, the dose may be increased to a maximum of 660 mg once daily.

PHN is a complication of herpes zoster or “shingles” infection in which the patient has continuing pain for months to years after the resolution of the shingles rash. In acute herpes zoster, the varicella-zoster virus causes inflammation of a peripheral nerve, dorsal root, and dorsal root ganglion that persists for up to 30 days. After resolution of the initial rash and inflammation, there can be fibrosis of the nerve which may be the cause of PHN. Diagnosis of PHN is made based on clinical symptoms when pain persists beyond four months in the same distribution as a preceding documented episode of acute herpes zoster. Treatment options include tricyclic antidepressants (e.g. amitriptyline), gabapentin, pregabalin, and topical agents such as topical lidocaine.

DPN is primarily a symmetrical sensory polyneuropathy that initially affects the lower extremities as a result of nerve damage caused by elevated blood glucose levels. Patients with DPN typically present with loss of sensation in their feet and decreased or absent ankle reflexes, but may also present with pain, paresthesias, or dysesthesias of their feet. The American Academy of Neurology (AAN) guidelines for the treatment of painful diabetic neuropathy were published in 2011 (before Lyrica CR became available) and recommend pregabalin as an effective treatment and venlafaxine, duloxetine, amitriptyline, and valproic acid as probably effective.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Lyrica CR is approved for the management of neuropathic pain associated with DPN and for PHN. Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.

Rationale/Source

Support for efficacy of Lyrica CR for the management of PHN and DPN was based on the efficacy of Lyrica for these indications along with a placebo controlled trial of Lyrica CR in patients with PHN. This study included patients with pain present for more than 3 months after healing of the herpes zoster skin rash and a baseline pain score ≥4 on the numeric rating scale-pain. Patients were first enrolled in the single-blind phase of the study in which all participants received Lyrica CR. Those who had at least a 50% reduction in pain in the single-blind phase were randomized in the double blind phase to either treatment with the Lyrica CR dose achieved in the single-blind phase or placebo. Patients were treated for up to 3 months following randomization. Lyrica CR treatment demonstrated statistically significant improvement in the endpoint change in mean pain score from baseline compared to placebo. In the Lyrica CR group, 79.8% of patients achieved at least a 30% improvement and 73.6% at least 50% improvement in pain intensity. In the placebo group, 64.9% of subjects achieved at least a 30% improvement and 54.6% at least a 50% improvement in pain intensity.

Lyrica CR was not directly compared to immediate release Lyrica or to other therapeutic agents for PHN or DPN. The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests the alternative therapeutic agents for PHN or DPN will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data, in the absence of the above caveats, there is not enough information to determine an advantage to using Lyrica CR over the commonly used standards of therapy for PHN or DPN.

References

1. Lyrica CR [package insert]. Parke-Davis Div of Pfizer, Inc. New York City, New York.
2. Bril V, England J, Franklin GM, Backonja M, Cohen J, Del Toro D, Feldman E, Iverson DJ, Perkins B, Russell JW, Zochodne D. 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. May 2011;76(20):1758-65.

Policy History

Original Effective Date: 05/16/2018
Current Effective Date: 05/16/2018
05/03/2018 Medical Policy Committee review
05/16/2018 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 05/2019

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*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.