Effective Date **8/1/2023**
Next Review Date **8/1/2024**
Coverage Policy Number **IP0183**

Pregabalin Extended-Release

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following products:

- **Lyrica® CR** (pregabalin extended-release) tablet
- **Pregabalin ER** (pregabalin extended-release) tablet

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage for pregabalin extended-release varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and Preferred Covered Alternatives:

Non-Covered Product	Preferred Covered Alternatives
Lyrica CR (pregabalin extended-release) 82.5 mg, 165 mg, 330 mg tablet **pregabalin ER** (pregabalin extended-release) 82.5 mg, 165 mg, 330 mg tablet	Individual meets **ONE** of the following (1 or 2): 1. **Neuropathic Pain Associated with Diabetic Peripheral Neuropathy (DPN).** A. There is documentation the individual has had an inadequate response, contraindication, or is intolerant, to the following: i. Pregalin immediate-release capsule or solution 2. **Postherpetic Neuralgia.** A. There is documentation the individual has had an inadequate response, contraindication, or is intolerant, to the following: i. Pregalin immediate-release capsule or solution

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Any other exception is considered not medically necessary.

Reauthorization Criteria

Pregabalin extended-release is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval and reauthorization duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven including the following (this list may not be all inclusive):

1. **Fibromyalgia.** A double-blind, placebo-controlled, randomized withdrawal trial of Lyrica CR in adults with fibromyalgia failed to demonstrate efficacy.[1]
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.[1]
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.

Background

OVERVIEW
Pregabalin extended-release tablets, an analog of gamma-aminobutyric acid (GABA), are indicated for the following uses:[1]

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

The efficacy of pregabalin extended-release tablets has not been established for the management of fibromyalgia or as adjunctive therapy for adults with partial onset seizures.[1]

Gabapentin immediate-release (IR), an analog of GABA, is indicated for the following uses:[2]

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

Pregabalin IR capsules and oral solution are indicated for the following uses:[3]

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

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.[4] 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 because 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.[5] The early recognition and appropriate management of neuropathy in the patient with diabetes is important. Up to 50% of 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%).[6] If not recognized and if preventive foot care is not implemented, patients are at risk for injuries to their insensate feet.[5] 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.[4-11] Guidelines do not address pregabalin extended-release tablets.

References

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3. Lyrica capsules and oral solution [prescribing information]. New York, NY: Pfizer; April 2020.
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.
5. American Diabetes Association Professional Practice Committee; 12. Retinopathy, Neuropathy, and Foot Care: *Standards of Medical Care in Diabetes—2023*. *Diabetes Care.* 2023;46 (Supplement_1):S203-S215. Available at: https://diabetesjournals.org/care/issue/46/Supplement_1. Accessed on March 9, 2023.
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8. Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2017;76:e54.
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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11. Garcia-Borreguero D, Silber MH, Winkelman JW, et al. Guidelines for the first-line treatment of restless legs syndrome/Willis–Ekbom disease, prevention and treatment of dopaminergic augmentation: a combined task force of the IRLSSG, EURLSSG, and the RLS-foundation. *Sleep Med*. 2016;21:1-11.

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