

PRIOR AUTHORIZATION WITH STEP THERAPY POLICY

POLICY: Neurology – Lyrica CR Prior Authorization with Step Therapy Policy

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

REVIEW DATE: 04/03/2024

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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of pregabalin extended-release tablets. Additionally, due to the availability of generic pregabalin extended-release tablets, approval of a branded pregabalin extended-release product requires a previous trial of the generic. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of pregabalin extended-release tablets is recommended in those who meet one of the following criteria:

FDA-Approved Indications

- 1. Neuropathic Pain Associated with Diabetic Peripheral Neuropathy.** Approve pregabalin extended-release tablets for 1 year if the patient meets the following (A and B):
 - A) Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic immediate-release 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] between the brand and the bioequivalent generic product, which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

- 2. Postherpetic Neuralgia.** Approve pregabalin extended-release tablets for 1 year if the patient meets the following (A and B):
 - A) Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic immediate-release 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] between the brand and the bioequivalent generic product, which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of pregabalin extended-release tablets is not recommended in the following situations:

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

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.

REFERENCES

1. Lyrica® CR extended-release tablets [prescribing information]. New York, NY: Pfizer; April 2020.
2. Neurontin® capsules, tablets, oral solution [prescribing information]. New York, NY: Pfizer; December 2020.
3. Lyrica capsules and oral solution [prescribing information]. Morgantown, WV: Viartis; December 2023.
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—2024*. *Diabetes Care*. 2023;47 (Supplement 1):S231-S243. Available at: [Volume 47 Issue Supplement 1 | Diabetes Care | American Diabetes Association \(diabetesjournals.org\)](https://diabetesjournals.org/standards/supplemental/Volume_47_Issue_Supplement_1_Diabetes_Care_American_Diabetes_Association). Accessed on March 28, 2024.
6. Price R, Smith D, Franklin G, et al. Oral and topical treatment of painful diabetic polyneuropathy: Practice Guideline update summary. Report of the AAN Guideline Subcommittee. *Neurology*. 2022;98(1):31-43.
7. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinology clinical practice guideline: Developing a diabetes mellitus comprehensive care plan – 2022 update. *Endocr Pract*. 2022;28(10):P923-1049.
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.
10. Khan M. Restless Legs Syndrome and Other Common Sleep-Related Movement Disorders. *Continuum (Minneapolis)*. 2023;29(4):1130-1148.
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.