

Federal Employee Program.

## LYRICA/ LYRICA CR\* (pregabalin)

\*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

#### RATIONALE FOR INCLUSION IN PA PROGRAM

## **Background**

Lyrica is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, management of post-herpetic neuralgia, management of fibromyalgia, and management of neuropathic pain associated with spinal cord injury in patients 18 years of age and older, and adjunctive therapy for adults and children 1 month of age and older with partial onset seizures. Lyrica CR is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and management of post-herpetic neuralgia. Lyrica and Lyrica CR are structural derivatives of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), although it does not bind directly to GABA<sub>A</sub>, GABA<sub>B</sub> or benzodiazepine receptors (1-2).

### **Regulatory Status**

FDA-approved indications:

Lyrica is indicated for: (1)

- Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- 2. Post-herpetic neuralgia (PHN)
- 3. Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older
- 4. Fibromyalgia
- 5. Neuropathic pain associated with spinal cord injury

### Lyrica CR is indicated for: (2)

- 1. Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- 2. Post-herpetic neuralgia (PHN)

#### <u>Limitations of Use</u>: (2)

Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult or children 4 years of age or older with partial onset seizures.



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Lyrica and Lyrica CR are controlled substances due to their potential for euphoric effects, abuse and dependence. Patients should be monitored for angioedema, ocular conditions, increased seizure frequency, increased suicidal thoughts or behavior, peripheral edema, creatinine kinase elevations, decreased platelet count, dizziness, and somnolence. When discontinuing Lyrica and Lyrica CR, the dose should be gradually tapered over a minimum of one week to minimize the potential of increased seizure frequency in patients with seizure disorders. Dosing regimens of Lyrica and Lyrica CR are specific to the indication and require dose adjustment for renal impairment (1-2).

The safety and effectiveness of Lyrica in pediatric patients 1 month of age and older with partialonset seizures have been established (1).

The safety and effectiveness of Lyrica CR in pediatric patients have not been established (2).

#### **Summary**

Lyrica is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, management of post-herpetic neuralgia, management of fibromyalgia, and management of neuropathic pain associated with spinal cord injury in adult patients, and adjunctive therapy for adults and children 1 month and older with partial onset seizures. Lyrica CR is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and management of post-herpetic neuralgia. Lyrica and Lyrica CR are controlled substances due to its potential for euphoric effects, abuse, and dependence. When discontinuing Lyrica and Lyrica CR, the dose should be gradually tapered over a minimum of one week. Dosing regimens of Lyrica and Lyrica CR are specific to the indication and require dose adjustment for renal impairment (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Lyrica and Lyrica CR while maintaining optimal therapeutic outcomes.

#### References

1. Lyrica [package insert]. Morgantown, WV: Viatris Inc.; December 2023.



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Lyrica/ Lyrica CR FEP Clinical Rationale

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2.	Lyrica CR [package insert]. New York, NY: Pfizer Pharmaceuticals, Inc.; June 2020.	