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5.75.018

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	May 26, 2017
Subject:	Lyrica	**Page:**	1 of 6

Last Review Date: December 13, 2024

Lyrica

Description

Lyrica, Lyrica CR* (pregabalin)

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

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 $GABA_A$, $GABA_B$ or benzodiazepine receptors (1-2).

Regulatory Status

FDA-approved indications:

Lyrica is indicated for: (1)

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)

Limitations of Use: (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.

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 partial-onset seizures have been established (1).

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

Related policies
Gabapentin, Savella

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lyrica and Lyrica CR may be considered **medically necessary** if the conditions indicated below are met.

Lyrica and Lyrica CR may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 month of age or older

Diagnosis

Patient must have the following:

Lyrica ONLY

1. Partial onset seizures
   a. Used in combination with other first line anti-epileptic medications
   b. **NO** dual therapy with gabapentin

Age 18 years of age or older

Diagnoses

Lyrica and Lyrica CR

Patient must have **ONE** of the following:

1. Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
2. Post-herpetic neuralgia (PHN)
3. Lyrica **only**: Neuropathic pain associated with spinal cord injury
4. Lyrica **only**: Fibromyalgia

AND the following for **ALL** diagnoses:

a. **NO** dual therapy with gabapentin

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 18 years of age or older

Quantity

Lyrica

Strength	Quantity Limit

25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg	600 mg per day
20mg/mL solution	

Prior - Approval Limits

Age 1 month of age to 17 years of age

Quantity

Lyrica

Strength	Quantity Limit
25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg	600 mg per day
20mg/mL solution	

Duration 24 months

Age 18 years of age and older

Quantity

Lyrica

Strength	Quantity Limit
25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg	Pre-PA allows for the FDA recommended maximum dosage
20 mg/ml solution	

Medication with approved FE only	Quantity Limit
Lyrica CR 82.5 mg, 165 mg, 330 mg	660 mg per day

Duration 24 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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

Policy History

Date	Action
May 2017	Addition to PA
June 2017	Annual review
December 2017	Addition of Lyrica CR
March 2018	Annual review
June 2018	Annual editorial review and reference update Age for PA allowance for Lyrica changed to 4 years of age and older for the diagnosis of partial onset seizures. Removal of tapers from criteria Addition of no dual therapy with gabapentin
June 2019	Reduced age requirement for Lyrica for partial onset seizures to 1 month and older
September 2019	Annual review and reference update
December 2019	Annual review. Moved Lyrica CR to MFE with PA only
September 2020	Annual review and reference update

December 2020	Annual review
June 2021	Annual review
June 2022	Annual review
December 2022	Annual review. Changed policy number to 5.75.018
February 2023	Revised quantity charts to remove specific quantities and set all dosage forms and strengths at 600 mg per day for Lyrica and 660 mg per day for Lyrica CR
March 2023	Annual review
December 2023	Annual review
June 2024	Annual review
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.