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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	May 26, 2017
Subject:	Lyrica	**Page:**	1 of 6

Last Review Date: June 16, 2022

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 indication:
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 may be considered **medically necessary** in patients that are 18 years of age and older with neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, fibromyalgia, and neuropathic pain associated with spinal cord injury or adjunctive therapy for adult patients and children 1 month of age and older with partial onset seizures and if the conditions indicated below are met.

Lyrica CR may be considered **medically necessary** in patients that are 18 years of age and older with neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia.

Lyrica may be considered **investigational** in patients that are less than 4 year of age and for all other indications.

Lyrica CR may be considered **investigational** in patients that are less than 18 year of age and 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

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

Lyrica CR

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

Lyrica

1. Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
2. Post-herpetic neuralgia (PHN)
3. Neuropathic pain associated with spinal cord injury
4. 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	540 dosage units per 90 days **OR**
150mg	360 dosage units per 90 days **OR**
200mg	270 dosage units per 90 days **OR**
225mg, 300mg	180 dosage units per 90 days **OR**
20mg/mL solution	2700mL per 90 days

Maximum daily limit of any combination: 600mg

Prior - Approval Limits

Age 1 month of age to 17 years of age

Quantity

Lyrica

Strength	Quantity Limit
25mg, 50mg, 75mg, 100mg	540 dosage units per 90 days **OR**
150mg	360 dosage units per 90 days **OR**
200mg	270 dosage units per 90 days **OR**
225mg, 300mg	180 dosage units per 90 days **OR**
20mg/mL solution	2700mL per 90 days

Maximum daily limit of any combination: 600mg

Duration 24 months

Age 18 years of age and older

Quantity

Lyrica

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

Medication with approved MFE only	Quantity Limit
Lyrica CR 82.5 mg, 165 mg	360 dosage units per 90 days **OR**
Lyrica CR 330mg	180 dosage units per 90 days

Maximum daily limit of any combination: 660mg

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]. New York, NY: Pfizer Pharmaceuticals, Inc.; June 2020.
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.