PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

LYRICA
(pregabalin)

LYRICA CR
(pregabalin extended-release)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Lyrica
Lyrica is indicated for:
- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for the treatment of partial onset seizures in patients 1 month of age and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

Lyrica CR
Lyrica CR is indicated for the management of:
- Neuropathic pain associated with diabetic peripheral neuropathy
- Postherpetic neuralgia

Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.

Compendial Uses
Lyrica
- Cancer-Related Neuropathic Pain[10]
- Cancer Treatment-Related Neuropathic Pain[10]

COVERAGE CRITERIA

Adjunctive Therapy for the Treatment of Partial Onset Seizures (i.e., Focal-Onset Seizures) in a Patient 1 Month to Up to 3 Years of Age, Cancer-Related Neuropathic Pain, Cancer Treatment-Related Neuropathic Pain, Fibromyalgia, Neuropathic Pain Associated with Spinal Cord Injury
Authorization may be granted for the requested drug when ALL of the following criteria is met:
- The request is for Lyrica (pregabalin immediate-release)
- The requested drug is being prescribed for ONE of the following:
    - Adjunctive therapy for the treatment of partial onset seizures (i.e., focal-onset seizures) in a patient 1 month to up to 3 years of age
    - Cancer-related neuropathic pain
    - Cancer treatment-related neuropathic pain

    - Management of fibromyalgia
    - Management of neuropathic pain associated with spinal cord injury
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
    - Requires a dose that cannot be obtained using the commercially available capsules

Adjunctive Therapy for the Treatment of Partial Onset Seizures (i.e., Focal-Onset Seizures) in a Patient 3 Years of Age or Older
Authorization may be granted when the requested drug is being prescribed for adjunctive therapy for the treatment of partial onset seizures (i.e., focal-onset seizures) in a patient 3 years of age or older when ALL of the following criteria is met:

- The request is for Lyrica (pregabalin immediate-release)
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
    - Requires a dose that cannot be obtained using the commercially available capsules
- The patient experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy
Authorization may be granted when the requested drug is being prescribed for the management of neuropathic pain associated with diabetic peripheral neuropathy when ONE of the following criteria are met:

- The request is for Lyrica (pregabalin immediate-release) and ALL of the following criteria are met:
    - If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
        - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
        - Requires a dose that cannot be obtained using the commercially available capsules
    - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release
- The request is for Lyrica CR (pregabalin extended-release) and ALL of the following criteria are met:
    - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following:
        - Gabapentin immediate-release
        - Pregabalin immediate-release
        - Duloxetine
        - Venlafaxine
        - A tricyclic antidepressant

Postherpetic Neuralgia
Authorization may be granted when the requested drug is being prescribed for the management of postherpetic neuralgia when ALL of the following criteria is met:

- The request is for Lyrica (pregabalin immediate-release) OR Lyrica CR (pregabalin extended-release)
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
    - Requires a dose that cannot be obtained using the commercially available capsules
- The patient experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release

CONTINUATION OF THERAPY

Adjunctive Therapy for the Treatment of Partial Onset Seizures (i.e., Focal-Onset Seizures) in a Patient 1 Month to Up to 3 Years of Age, Adjunctive Therapy for the Treatment of Partial Onset Seizures (i.e., Focal-Onset Seizures) in a Patient 3 Years of Age or Older, Cancer-Related Neuropathic Pain, Cancer Treatment-Related Neuropathic Pain, Fibromyalgia, Neuropathic Pain Associated with Spinal Cord Injury
Authorization may be granted for the requested drug when ALL of the following criteria is met:

- The request is for Lyrica (pregabalin immediate-release)

- The requested drug is being prescribed for ONE of the following:
    - Adjunctive therapy for the treatment of partial onset seizures (i.e., focal-onset seizures) in a patient 1 month to up to 3 years of age
    - Adjunctive therapy for the treatment of partial onset seizures (i.e., focal-onset seizures) in a patient 3 years of age or older
    - Cancer-related neuropathic pain
    - Cancer treatment-related neuropathic pain
    - Management of fibromyalgia
    - Management of neuropathic pain associated with spinal cord injury
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
    - Requires a dose that cannot be obtained using the commercially available capsules
- The patient has achieved or maintained a positive clinical response to the requested drug

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy
Authorization may be granted when the requested drug is being prescribed for the management of neuropathic pain associated with diabetic peripheral neuropathy when ALL of the following criteria is met:

- The request is for Lyrica (pregabalin immediate-release) OR Lyrica CR (pregabalin extended-release)
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
    - Requires a dose that cannot be obtained using the commercially available capsules
- The patient has achieved or maintained a positive clinical response to the requested drug

Postherpetic Neuralgia
Authorization may be granted when the requested drug is being prescribed for the management of postherpetic neuralgia when ALL of the following criteria is met:

- The request is for Lyrica (pregabalin immediate-release) OR Lyrica CR (pregabalin extended-release)
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules)
    - Requires a dose that cannot be obtained using the commercially available capsules
- The patient has achieved or maintained a positive clinical response to the requested drug

DURATION OF APPROVAL (DOA)

- 594-A: DOA: 36 months
- 913-A: DOA: 12 months

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