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Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C4709-A

Lyrica and Lyrica CR (pregabalin and pregabalin ER)

PRODUCTS AFFECTED

Lyrica (pregabalin), Lyrica CR (pregabalin ER), Lyrica Soln (pregabalin), pregabalin, pregabalin ER, pregabalin soln

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neuropathic pain associated with diabetic peripheral neuropathy, Post herpetic neuralgia, Partial onset seizures, Fibromyalgia, Neuropathic pain associated with spinal cord injury

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NEUROPATHIC PAIN (ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY, OR POST HERPETIC NEURALGIA):
   1. Documented diagnosis of neuropathic pain associated with diabetic peripheral neuropathy

(DPN), or post herpetic neuralgia (PHN)
AND

2. Documentation of treatment failure, serious side effects, or clinical contraindication to TWO of the following:
   (a) Gabapentin (at maximally tolerated dosing of a minimum of least 100-300mg three times per day- exception for dose reductions required for renal function)
   (b) Duloxetine
   (c) Lidocaine patches 4% (OTC)
   (d) A tricyclic antidepressant (e.g., amitriptyline)

   AND
3. FOR LYRICA CR: Member has a prior trial of immediate-release form of pregabalin AND documentation member's creatinine clearance is greater than 30mls/minute AND prescriber provides a medical rationale that Lyrica CR is clinically necessary

B. FIBROMYALGIA (IMMEDIATE RELEASE ONLY):
1. Documentation of a diagnosis of fibromyalgia
   AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to ALL of the following:
   (a) Therapeutic dosing of gabapentin (1200mg-2400mg daily)
   AND
   (b) A 30-day trial of duloxetine at up to maximally indicated doses
   AND
   (c) A 30-day trial of cyclobenzaprine or a tricyclic antidepressant (TCA) at up to maximally indicated doses, unless member's age is ≥ 65

C. PARTIAL ONSET SEIZURES (IMMEDIATE RELEASE ONLY):
1. Documented diagnosis of partial onset seizure disorder
   AND
2. Prescriber attests or clinical reviewer has found that there is a therapeutic plan demonstrating pregabalin will be used as adjunctive therapy and not monotherapy

D. NEUROPATH PAIN ASSOCIATED WITH SPINAL CORD INJURY (IMMEDIATE RELEASE ONLY):
1. Documented diagnosis of neuropathic pain associated with spinal cord injury

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months.

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:

PERIPHERAL NEUROPATHY, POST HEPATIC NEURALGIA, FIBROMYALGIA, SPINAL CORD INJURY: 18 years of age and older
PARTIAL ONSET SEIZURES: 1 month of age and older

QUANTITY:
Immediate-release formulations:
300 mg/day PO for diabetic peripheral neuropathy
600 mg/day PO for post herpetic neuralgia, adjunctive treatment of seizures and spinal cord injury
450 mg/day PO for fibromyalgia.

Extended-release tablets:
330 mg/day PO for diabetic peripheral neuropathy
660 mg/ day PO for post herpetic neuralgia

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Anticonvulsants - Misc.

FDA-APPROVED USES:
Lyrica (pregabalin) is indicated for:

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

Lyrica CR (pregabalin extended release) is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and post herpetic neuralgia (PHN)

COMPENDIAL APPROVED OFF-LABELED USES:
Cancer-related neuropathic pain, Generalized anxiety disorder

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Lyrica CR is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). The efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures. Lyrica CR is an analog of the neurotransmitter gamma- aminobutyric acid (GABA). Lyrica CR is dosed once daily (QD), and it is a Schedule V controlled substance.

Cancer Related Neuropathy

NCCN guidelines include the use of anticonvulsants as first-line adjuvant analgesics for the treatment of cancer related neuropathic pain. This includes pregabalin. Noted starting dose of 75mg twice a day with increasing dose increments every 3 days to a maximum of 600mg daily. Refer to NCCN guidelines for management of adult cancer pain.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Lyrica & Lyrica CR (pregabalin & pregabalin extended release) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Contraindications to pregabalin include: hypersensitivity to pregabalin or any of its components.

OTHER SPECIAL CONSIDERATIONS:

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

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Lyrica CAPS 25MG, 50MG, 75MG, 100MG, 150MG, 200MG, 225MG, 300MG
Lyrica CR TB24 82.5MG, 165MG, 330MG
Lyrica SOLN 20MG/ML
Pregabalin CAPS 25MG, 50MG, 75 MG, 100MG, 150MG, 200MG, 225MG, 300MG
Pregabalin ER TB24 82.5MG, 165MG, 330MG
Pregabalin SOLN 20MG/ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy References	Q1 2025
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions Compendial Approved Off-Labeled Uses Background Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file