UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 3019-15
Program	Step Therapy
Medication	Lyrica CR tablets* (pregabalin)
P&T Approval Date	1/08, 4/2009, 5/2010, 3/2011, 2/2012, 2/2013, 5/2013, 5/2014, 2/2015; 2/2016, 4/2016, 10/2016, 2/2017, 3/2018, 3/2019, 9/2019, 9/2020, 9/2021, 1/2023
Effective Date	4/1/2023; Oxford only: 4/1/2023

1. Background:

Lyrica CR (pregabalin) tablets are FDA approved for neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia. Lyrica CR is not approved for partial onset seizures or fibromyalgia as clinical trials failed to demonstrate efficacy for these indications. The National Comprehensive Cancer Network recognizes antiepileptic drugs, including gabapentin and Lyrica, for treatment of chemotherapy-induced peripheral neuropathy.

2. Coverage Criteria[a]:

A. Lyrica CR* will be approved based on ONE of the following:

1. **BOTH** of the following:

   a. Diagnosis of neuropathic pain and history of failure, contraindication, or intolerance to **two** of the following medications (document date of trial and drug name):

      (1) gabapentin (generic Neurontin)
      (2) One (1) serotonin-norepinephrine reuptake inhibitor (e.g., duloxetine [generic Cymbalta])
      (3) One (1) tricyclic antidepressant (e.g., amitriptyline)

   -AND-

   b. History of failure, contraindication, or intolerance to pregabalin (generic Lyrica) immediate release capsules or solution (document date of trial and reason for failure)

   -OR-

2. All other diagnoses not specified above (Note: Any diagnosis associated with nerve pain would require review as neuropathic pain) and history of failure, contraindication or intolerance to **BOTH** of the following (document the diagnosis and date of trial):

   a. gabapentin (generic Neurontin)
   b. pregabalin (generic Lyrica) immediate release capsules or solution

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Lyrica CR is typically excluded from coverage

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

1. Lyrica CR [package insert]. New York, NY: Pfizer Inc.; June 2020.
2. Dubinsky RM, Kabbani H, El-Chami Z, et al. Practice Parameter: Treatment of postherpetic neuralgia: An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2004;63(6):959-65.
3. Bril V, England J, Franklin GM, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. 2011; 76(20):1758-1765.
4. Tesfaye S, Boulton AJM, Dyck PJ et al. Diabetic Neuropathies: Update on Definitions, Diagnostic Criteria, Estimation of Severity, and Treatments. Diabetes Care. 2010;33(10):2285-93.
5. Handelsman Y, Mechanick JI, Blonde L, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan. Endocr Pract. 2011;17(Suppl 2):1-53.
6. Swarm R, Youngwerth J, Anghelescu D, et al. National Comprehensive Cancer Network Adult Cancer Pain Guidelines. National Comprehensive Cancer Network, Inc. June 2022;Pain-F:1-2

Program	Step Therapy - Lyrica®(pregabalin)
Change Control	
5/2014	Annual Review. Updated references.
2/2015	Added step criteria for fibromyalgia. Included additional references. New program for Book of Business.
2/2016	Annual review. Minor wording change to background. Decreased authorization period from 60 months to 24 months.
4/2016	Added requirement for documentation of drug, date and duration of medication trials. Added criteria for generalized anxiety disorder. Added clarification around the diagnosis of "other" that it should not be a diagnosis that better fits under neuropathy or fibromyalgia.
7/2016	Added Indiana and West Virginia coverage information.

10/2016	Minor wording changes to criteria to more clearly identify that prior trials of medications should be documented. Changed authorization period to 12 months. Added California coverage information.
2/2017	Added criteria for members new to plan who are currently stable on Lyrica.
3/2018	Added Lyrica CR. Revised state mandate language. Revised requirement for members new to the plan.
12/2018	Administrative change to add statement regarding use of automated processes.
3/2019	Annual review. Updated references.
10/2019	Removed Lyrica IR from criteria.
9/2020	Annual review. Updated references.
9/2021	Annual review. Updated step alternatives from duloxetine to any SNRI. Updated references.
1/2023	Annual review. Updated references.