



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3019-13
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
Effective Date	12/1/2020; Oxford only: 12/1/2020

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.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. If the member has evidence of Lyrica Capsules or Solution and an antiepileptic drug in the claims history, then Lyrica Capsules or Solution will automatically process.

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):

- (1) gabapentin (generic Neurontin)
- (2) duloxetine (generic Cymbalta)
- (3) One (1) tricyclic antidepressant (e.g. amitriptyline), (Document Drug name)

-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) and history of failure, contraindication or intolerance to **BOTH** of the following: (Document the diagnosis and ensure that the diagnosis is not associated with nerve pain which would require review as neuropathic pain. (Document 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 [Prescribing Information]. 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. <http://www.uptodate.com/contents/initial-treatment-of-fibromyalgia-in-adults#H95200969>.
7. Clauw DJ. Fibromyalgia: a clinical review. *JAMA*. 2014 Apr 16;311(15):1547-55
8. Fitzcharles MA, et al. National Fibromyalgia Guideline Advisory Panel. 2012 Canadian guidelines for the diagnosis and management of fibromyalgia syndrome: executive summary. *Pain Res Manag*. 2013;18(3):119-126.
9. Bandelow B, et al. Guidelines for the pharmacological treatment of anxiety disorders, obsessive – compulsive disorder and posttraumatic stress disorder in primary care. *Int J Psych Clin Practice*. 2012; 16:77-84.



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.