UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lyrica

Program	Prior Authorization
Medication	Lyrica capsules, Lyrica Solution, Lyrica CR tablets (pregabalin)
Markets in Scope	Arizona, Hawaii, New Jersey, New York, New York EPP, Pennsylvania- CHIP, California, South Carolina, Nevada
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Lyrica (pregabalin) capsules and solution are FDA-approved for adjunctive therapy of partial onset seizures, post herpetic neuralgia, neuropathic pain associated with diabetic peripheral neuropathy, fibromyalgia, and neuropathic pain associated with spinal cord injury. 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.

2. Coverage Criteria:

A. **BRAND Lyrica** immediate-release capsules or solution will be approved based on **one** of the following criteria:

1. **Both** of the following:

   a. Diagnosis of one of the following:
      - Fibromyalgia
      - Diabetic peripheral neuropathy (DPN)
      - Post herpetic neuralgia (PHN)
      - Neuropathic pain associated with spinal cord injury

   -AND-

   b. History of failure to generic pregabalin manufactured by Greenstone at a minimum dose of 300mg daily for 4 weeks, or contraindication or intolerance to generic pregabalin manufactured by Greenstone

-OR-

2. Lyrica is being requested for the treatment of a seizure disorder

Authorization will be issued for 12 months.

B. **Lyrica CR** will be approved based on **one** of the following criteria:

1. Diagnosis of diabetic peripheral neuropathy (DPN) with **all** of the following:
   a. History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800mg daily for 4 weeks

-AND-

   b. History of failure, contraindication, or intolerance to treatment with **one** of the following:
      (1) Tricyclic antidepressant at the maximum tolerated dose for 6 – 8 weeks, or intolerance to a tricyclic antidepressant
      (2) SNRI antidepressant (e.g., duloxetine, venlafaxine)

-AND-

   c. History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules manufactured by Greenstone or generic pregabalin suspension

-OR-

2. Diagnosis of post herpetic neuralgia (PHN) with **all** of the following:
   a. History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800mg daily for 4 weeks

-AND-

   b. History of failure, contraindication, or intolerance to a tricyclic antidepressant at the maximum tolerated dose for 6 – 8 weeks

-AND-

   c. History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules manufactured by Greenstone or generic pregabalin suspension

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- 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 be in place.

4. References:

1. Lyrica [package insert]. New York, NY: Pfizer Inc.; April 2020.
2. Lyrica CR [package insert]. New York, NY: Pfizer Inc.; April 2020.
3. Pop-Busui R, Boulton AJM, Feldman AL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. 2017; 40: 136-154.
4. 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.
5. Bajwa ZH, Ortega E. Postherpetic Neuralgia. UptoDate. Feb 2017. Accessed May 2017.
6. Johnson RW, Rice ASC. Postherpetic Neuralgia. N Engl J Med. 2014; 371: 1526-33.
7. 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.
8. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists And American College of Endocrinology Clinical Practice Guidelinesfor Developing a Diabetes Mellitus Comprehensive Care Plan. Endocr Pract. 2015;21(Suppl 1):1-87.
9. Stubblefield, MD, Burstein, HJ, Burton, AW NCCN Task Force Report: Management of Neuropathy in Cancer. JNCCN 2009;7[Suppl 5]:S1-S26.
10. Goldenburg DL. Initial treatment of fibromyalgia in adults. UptoDate. April 2016. http://www.uptodate.com/contents/initial-treatment-of-fibromyalgia-in-adults#H95200969.
11. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55
12. 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.
13. Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. Annals of the Rheumatic Diseases. 2017; 76: 318-328.

14. 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	Program type – Prior Authorization
Change Control	
Date	Change
6/2009	Criteria were taken from Unison's RX06 Neuropathic Pain / Fibromyalgia policy. Policy was reformatted. Cyclobenzaprine was added as an option for prerequisite fibromyalgia therapy and gabapentin was added as prerequisite therapy for seizures.
12/2010	Annual Review
12/2011	Annual Review
9/2012	Added new indication of neuropathic pain due to spinal cord injury to guideline. Neuropathic pain due to spinal cord injury is a new approved indication.
12/2015	Annual Review
3/31/16	Annual Review- Updated policy template and added duloxetine (generic Cymbalta) as an alternative for diabetic peripheral neuropathy diagnosis and fibromyalgia
7/2017	Updated policy template. Updated background. Revised step therapy criteria from trial of duloxetine to trial of an SNRI.
4/2018	Added Lyrica CR to the policy. Modified step through other drugs language for consistency. Removed cyclobenzaprine as a step therapy drug for fibromyalgia as it is not a recommended treatment regimen.
7/2018	Added continuation of therapy language for patients ongoing on Lyrica for a seizure disorder (consistent with the Anticonvulsants policy).
10/2018	Updated criteria to allow for Lyrica IR and oral solution for Diagnosis to Drug Match for seizures only. Updated references.
10/2019	Changed criteria to evaluate for brand medically necessary requests.
10/2020	Annual review. Updated references. Added clinical rules section. No changes to clinical criteria.