UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lyrica

Program	Prior Authorization
Medication	Lyrica (pregabalin)
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

1. Background:

Lyrica (pregabalin) is FDA approved foradjunctive therapy of partial onset seizures, post herpetic neuralgia, neuropathic pain associated with diabetic peripheral neuropathy, fibromyalgia, and neuropathic pain associated with spinal cord injury.

2. Coverage Criteria:

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

1. Diagnosis of seizure disorder with **both** of the following:
   a. History of inadequate response or intolerance to Gabapentin
   b. Lyrica is being used as adjunctive therapy

-OR-

2. Diagnosis of neuropathic pain associated with spinal cord injury with the following:
   a. Inadequate response to Gabapentin at a minimum dose of 1800mg daily for 4 weeks, or intolerance to Gabapentin.

-OR-

3. Diagnosis of fibromyalgia and history of failure, contraindication, or intolerance to **all** of the following:
   a. Inadequate response to Gabapentin (generic Neurontin) at a minimum dose of 1800mg daily for 4 weeks, or intolerance to Gabapentin

-AND-

   b. Inadequate response or intolerance to treatment with **one** of the following:
      (1) Tricyclic Antidepressant at the maximum tolerated dose for 6 – 8 weeks; **OR**

      (2) Selective Serotonin Reuptake Inhibitor (SSRI) at the maximum

tolerated dose for 6 – 8 weeks; **OR**

(3) Serotonin and Norepinephrine Reuptake Inhibitor (SNRI) at the maximum tolerated dose for 6 – 8 weeks; **OR**

(4) Cyclobenzaprine

-OR-

4. Diagnosis of diabetic peripheral neuropathy (DPN) with **all** of the following:
   a. Inadequate response to Gabapentin at a minimum dose of 1800mg daily for 4 weeks, or intolerance to Gabapentin.

-AND-

   b. Inadequate response 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; **OR**

      (2) SNRI anti-depressant (i.e. duloxetine, venlafaxine)

5. Diagnosis of post herpetic neuralgia (PHN) with **all** of the following:
   a. Inadequate response to Gabapentin at a minimum dose of 1800mg daily for 4 weeks, or intolerance to Gabapentin.

-AND-

   b. Inadequate response to a tricyclic antidepressant at the maximum tolerated dose for 6 – 8 weeks, or intolerance to a tricyclic antidepressant.

Authorization will be issued for 12 months.

3. References:

1. Lyrica® [prescribing information]. New York, NY: Pfizer Inc.; December 2016.
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3. 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.
4. Bajwa ZH, Ortega E. Postherpetic Neuralgia. UptoDate. Feb 2017. Accessed May 2017.
5. Johnson RW, Rice ASC. Postherpetic Neuralgia. N Engl J Med. 2014; 371: 1526-33.
6. 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.

7. 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.
8. Stubblefield, MD, Burstein, HJ, Burton, AW NCCN Task Force Report: Management of Neuropathy in Cancer. JNCCN 2009;7[Suppl 5]:S1-S26.
9. Goldenburg DL. Initial treatment of fibromyalgia in adults. UptoDate. April 2016. http://www.uptodate.com/contents/initial-treatment-of-fibromyalgia-in-adults#H95200969.
10. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55
11. 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.
12. 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.
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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.