1. **Background:**

Lyrica capsules and solution (pregabalin) are FDA approved for seizures disorders, 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. The National Comprehensive Cancer Network recognizes antiepileptic drugs, including gabapentin and Lyrica for treatment of chemotherapy induced peripheral neuropathy.

Neuropathic pain is a complex, chronic pain state that usually is accompanied by tissue injury. With neuropathic pain, the nerve fibers themselves might be damaged, dysfunctional, or injured. These damaged nerve fibers send incorrect signals to other pain centers. Factors that can cause peripheral neuropathy include diabetes, injury, vitamin deficiency, kidney disease, alcoholism, cancer, exposure to toxins, shingles, HIV, Lyme disease, and others.

For the treatment of fibromyalgia, treatment guidelines and evidence support the following first-line agents: duloxetine, Savella (milnacipran), tricyclic antidepressants (e.g. amitriptyline), gabapentin, venlafaxine or Lyrica. Lyrica is recognized for the treatment of generalized anxiety disorder. There is no evidence to support the use of Lyrica for other behavioral health disorders.

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. **Lyrica immediate release capsules or solution** will be approved based on **one** of the following criteria:
1. Diagnosis of **one** of the following:
   a. Seizure disorder
   b. Neuropathic pain associated with spinal cord injury

   -OR-

2. Diagnosis of neuropathic pain and history of failure, contraindication, or intolerance to **two** of the following medications (Document drug, date and duration of trial):
   a. gabapentin (generic Neurontin)
   b. duloxetine (generic Cymbalta)
   c. One (1) tricyclic antidepressant (e.g. amitriptyline)

   -OR-

3. Diagnosis of fibromyalgia and history of failure, contraindication, or intolerance to **three** of the following medications (Document drug, date and duration of trial):
   a. gabapentin (generic Neurontin)
   b. Savella
   c. venlafaxine (generic Effexor, Effexor XR)
   d. duloxetine (generic Cymbalta)
   e. One (1) tricyclic antidepressant (e.g. amitriptyline)

   -OR-

4. Diagnosis of generalized anxiety disorder and history of failure, contraindication or intolerance to **three** of the following medications (Document drug, date and duration of trial):
   a. gabapentin (generic Neurontin)
   b. venlafaxine (generic Effexor, Effexor XR)
   c. duloxetine (generic Cymbalta)
   d. One or more selective serotonin reuptake inhibitors (SSRIs)

   -OR-

5. All other diagnoses (not specified above) and history of failure, contraindication or intolerance to gabapentin. (Document the diagnosis and ensure that the diagnosis is not associated with nerve pain which would require review as neuropathic pain or fibromyalgia(Document date and duration of trial)).

   -OR-

6. **BOTH** of the following:
   a. The member is currently stable on Lyrica.
b. **ONE** of the following:

(1) The member is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days).
(2) Member was previously new to the plan and approved for Lyrica

**Authorization will be issued for 12 months.**

**B. 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 drug, date and duration of trial):
      
      (1) gabapentin (generic Neurontin)
      (2) duloxetine (generic Cymbalta)
      (3) One (1) tricyclic antidepressant (e.g. amitriptyline)
   
   -AND-

   b. History of failure, contraindication, or intolerance to 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 and duration of trial)).

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

**Authorization will be issued for 12 months.**

*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.*

**3. Additional Clinical Programs:**

*Lyrica CR is typically excluded from coverage*
Supply limits may also be in place.

4. References:


<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy - Lyrica® (pregabalin)</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
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<tr>
<td>5/2014</td>
<td>Annual Review. Updated references.</td>
</tr>
<tr>
<td>2/2015</td>
<td>Added step criteria for fibromyalgia. Included additional references. New program for Book of Business.</td>
</tr>
<tr>
<td>2/2016</td>
<td>Annual review. Minor wording change to background. Decreased authorization period from 60 months to 24 months.</td>
</tr>
<tr>
<td>4/2016</td>
<td>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.</td>
</tr>
<tr>
<td>7/2016</td>
<td>Added Indiana and West Virginia coverage information.</td>
</tr>
<tr>
<td>Date</td>
<td>Updates</td>
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<tr>
<td>10/2016</td>
<td>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.</td>
</tr>
<tr>
<td>2/2017</td>
<td>Added criteria for members new to plan who are currently stable on Lyrica.</td>
</tr>
<tr>
<td>3/2018</td>
<td>Added Lyrica CR. Revised state mandate language. Revised requirement for members new to the plan.</td>
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