1. **Background:**

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Lyrica (pregabalin) is FDA approved for seizures disorders, post herpetic neuralgia, neuropathic pain associated with diabetic peripheral neuropathy, fibromyalgia and neuropathic pain associated with spinal cord injury. The National Comprehensive Cancer Network recognizes antiepileptic drugs, including gabapentin and Lyrica for treatment of chemotherapy induced peripheral neuropathy.

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.

This program requires a member to try gabapentin, duloxetine, or a tricyclic antidepressant before providing coverage for Lyrica for any type of neuropathic pain. (e.g. diabetic peripheral neuropathy, post herpetic neuralgia). 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.

In addition, this program will require a member to try at least three of the following five agents (gabapentin, Savella (milnacipran), tricyclic antidepressant, venlafaxine, or duloxetine) before providing coverage for Lyrica for fibromyalgia.

For generalized anxiety disorder, the member will need to try at least three of the following agents: gabapentin, venlafaxine, duloxetine, and one or more selective serotonin reuptake inhibitors (SSRIs). There is no evidence to support the use of Lyrica for other behavioral health disorders.

If the member has evidence of Lyrica and an antiepileptic drug in the claims history, then Lyrica will automatically process.
2. **Coverage Criteria**

   A. **Lyrica** 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).

      **-OR-**

   6. **BOTH** of the following:
a. The member is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days).

-AND-

b. The member is currently stable on Lyrica.

Authorization will be issued for 12 months.

For Maryland, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication in the past 180 days and that the medication is effective in treating the patient’s condition. Please see Maryland Continuation of Care guideline.

For Indiana (effective 7/1/16) and West Virginia (effective 1/1/17), step therapy requirements may be approved if the patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a preceding prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. For West Virginia (effective 1/1/17) members only, coverage may also be provided for continuation of therapy if the member is currently stabilized on the requested medication for the same medical condition.

For California, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication, it is appropriately prescribed, and that the medication is considered safe and effective in treating the patient’s condition.

3. **Additional Clinical Programs:**
   Supply limits may also be in place.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Change Control</th>
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<tbody>
<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>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>
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<tr>
<td>2/2017</td>
<td>Added criteria for members new to plan who are currently stable on Lyrica.</td>
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