## Overview

Pregabalin is a GABA analog which binds to alpha-2-delta subunit of voltage-gated calcium channels within the CNS and modulates calcium influx at the nerve terminals, thereby inhibiting excitatory neurotransmitter release including glutamate, norepinephrine (noradrenaline), serotonin, dopamine, substance P, and calcitonin gene-related peptide. Although structurally related to GABA, it does not bind to GABA or benzodiazepine receptors. Exerts antinociceptive and anticonvulsant activity. Pregabalin may also affect descending noradrenergic and serotonergic pain transmission pathways from the brainstem to the spinal cord.

### FDA-Approved Indications
1. Management of fibromyalgia (immediate release only)
2. Neuropathic pain associated with diabetic peripheral neuropathy (immediate release and ER) or postherpetic neuralgia*(immediate release and ER)
3. Neuropathic pain associated with spinal cord injury (immediate release only)
4. Seizures, focal (partial) onset (immediate release only).

### Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Lyrica for any FDA approved diagnosis, excluding when the product is obtained as samples or via manufacturer’s patient assistance program.

**OR**

Authorization may be granted if the member meets all the following diagnosis specific criteria and documentation has been submitted:

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### Pregabalin capsules (generic for Lyrica)

**Pregabalin 20mg/mL oral suspension**

**Effective 10/01/2020**

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<tr>
<th>Plan</th>
<th>Benefit</th>
<th>Program Type</th>
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<td>☒ MassHealth</td>
<td>☒ Pharmacy Benefit</td>
<td>☒ Prior Authorization</td>
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<tr>
<td>☒ Commercial/Exchange</td>
<td>☐ Medical Benefit (NLX)</td>
<td>☒ Quantity Limit</td>
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<tr>
<th>Specialty Limitations</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
<th>Medical Specialty Medications (NLX)</th>
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<tr>
<td>N/A</td>
<td>All Plans</td>
<td>MassHealth</td>
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<tr>
<td></td>
<td>Phone: 866-814-5506</td>
<td>Phone: 877-433-7643</td>
<td>Phone: 844-345-2803</td>
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<tr>
<td></td>
<td>Fax: 866-249-6155</td>
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<td>Fax: 855-582-2022</td>
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### Exceptions

N/A
Fibromyalgia
1. Member is ≥ 18 years of age
2. Member has had an inadequate response or adverse reaction to a trial of gabapentin
   AND
3. Member has had an inadequate response, adverse reaction or allergy to a trial of at least one agent from any of the following categories:
   • Tricyclic antidepressants
   • Cyclobenzaprine
   • SSRI
   • SNRI

Neuropathic pain associated with diabetic peripheral neuropathy or spinal cord injury or postherpetic neuralgia *
1. Member has had a documented inadequate response, side effect, or allergy to a trial of gabapentin
   AND
2. Member has had a documented inadequate response, side effect or allergy to one of the following:
   • Tricyclic antidepressants
   • Duloxetine
   • Venlafaxine

Seizure disorder [focal (partial) onset]
1. Member is ≥ 1 year old
2. Member will be using Lyrica as an adjunctive therapy
3. Member has had an inadequate response, side effect or allergy to a trial of two anticonvulsants

*Conditions associated with Neuropathic Pain:

<table>
<thead>
<tr>
<th>Peripheral neuropathy</th>
<th>Complex regional pain syndrome</th>
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<tbody>
<tr>
<td>Diabetic peripheral neuropathy</td>
<td>Neuropathic pain due to Multiple Sclerosis</td>
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<tr>
<td>Post herpetic neuropathy</td>
<td>Neuropathic pain due to cancer chemotherapy</td>
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<tr>
<td>Reflex sympathetic dystrophy</td>
<td>Neuropathic pain due to stroke</td>
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<tr>
<td>Phantom limb pain</td>
<td>Neuropathic pain due to traumatic nerve or spinal cord injury</td>
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<tr>
<td>Carpal tunnel syndrome</td>
<td>Neuropathic pain due to HIV/Hepatitis C</td>
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<tr>
<td>Sciatica</td>
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Limitations
1. Approvals will be granted for 36 months
2. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, &amp; 200mg</th>
<th>90 capsules</th>
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<tbody>
<tr>
<td>Pregabalin 225mg &amp; 300mg</td>
<td>60 capsules</td>
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<tr>
<td>Pregabalin 20mg/mL oral solution</td>
<td>900 mL</td>
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References
1. Lyrica (pregabalin) [prescribing information]. New York, NY: Pfizer Inc; June 2020


**Review History**

02/27/2006 – Reviewed
04/03/2006 – Implemented
09/24/2007 – Reviewed
11/05/2007 – Reviewed
09/22/2008 – Updated
09/21/2009 – Reviewed
09/27/2010 – Reviewed
09/19/2011 – Reviewed
09/24/2012 – Reviewed
12/01/2012 – Lyrica solution
09/23/2013 – Updated
04/07/2014 – Lyrica trials question re-wording “any of”
08/04/2014 – Duloxetine generic release
09/22/2014 – Table updated
09/21/2015 – Reviewed
09/19/2016 – Reviewed
09/18/2017 – Reviewed
09/24/2018 – Reviewed
09/18/2019 – Removed ST and created PA program
07/22/2020 – Reviewed and Updated July P&T Mtg; updated program type to PA and QL; updated criteria name to pregabalin; Limitations updated to reflect generic pregabalin. Effective 10/01/2020.

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