

**Pregabalin capsules (generic for Lyrica)
Pregabalin 20mg/mL oral suspension
Effective 10/01/2020**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

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:



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:**

Peripheral neuropathy	Complex regional pain syndrome
Diabetic peripheral neuropathy	Neuropathic pain due to Multiple Sclerosis
Post herpetic neuropathy	Neuropathic pain due to cancer chemotherapy
Reflex sympathetic dystrophy	Neuropathic pain due to stroke
Phantom limb pain	Neuropathic pain due to traumatic nerve or spinal cord injury
Carpal tunnel syndrome	Neuropathic pain due to HIV/Hepatitis C
Sciatica	

Limitations

1. Approvals will be granted for 36 months
2. The following quantity limits apply:

pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, & 200mg	90 capsules
pregabalin 225mg & 300mg	60 capsules
pregabalin 20 mg/mL oral solution	900 mL

References

1. Lyrica (pregabalin) [prescribing information]. New York, NY: Pfizer Inc; June 2020

2. Haanpää M, Cruccu G, Nurmikko TJ, et al. Capsaicin 8% patch versus oral pregabalin in patients with peripheral neuropathic pain. *Eur J Pain*. 2016;20(2):316-328
3. Feldman EL. Treatment of diabetic neuropathy. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed June 26, 2020
4. Majdinasab N, Kaveyani H, Azizi M. A comparative double-blind randomized study on the effectiveness of Duloxetine and Gabapentin on painful diabetic peripheral polyneuropathy. *Drug Des Devel Ther* 2019; 13:1985
5. Derry S, Cording M, Wiffen PJ, et al. Pregabalin for pain in fibromyalgia in adults. *Cochrane Database Syst Rev* 2016; 9:CD011790
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8. Lunn MP, Hughes RA, Wiffen PJ. Duloxetine for treating painful neuropathy, chronic pain or fibromyalgia. *Cochrane Database Syst Rev* 2014;:CD007115
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15. French J, Glue P, Friedman D, et al. Adjunctive pregabalin vs gabapentin for focal seizures: Interpretation of comparative outcomes. *Neurology* 2016; 87:1242
16. Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. *Diabetes Care* 2017; 40:136

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

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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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