Lyrica (pregabalin CR) Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace, FocusRx and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.

FDA APPROVED INDICATIONS AND DOSAGE[1]

<table>
<tr><th>Agent</th><th>Indications</th><th>Dosage</th></tr>
<tr><td>Lyrica CR®
(pregabalin ER)

tablets</td><td>Management of:
• Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
• Postherpetic neuralgia (PHN)

Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures</td><td>
<table>
<tr><th>Indication</th><th>Initial Dose</th><th>Maximum Daily Dose</th></tr>
<tr><td>DPN Pain</td><td>165 mg/day as a single dose</td><td>330 mg/day as a single dose within 1 week.</td></tr>
<tr><td>PHN</td><td>165 mg/day as a single dose</td><td>330 mg/day as a single dose within 1 week. Maximum dose of 660 mg/day once daily.</td></tr>
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CLINICAL RATIONALE

Diabetic peripheral neuropathy (DPN) develops as a late manifestation of uncontrolled or long-standing diabetes and is the most prevalent chronic complication of diabetes. Distal symmetric polyneuropathy (DSPN) is characterized by burning pain, paresthesias, and numbness that follows a stocking-glove pattern and progresses proximally. Poorly controlled blood glucose levels, especially greater variation in glucose levels, contribute to the occurrence and severity of painful DPN.[3] DSPN is the most important cause of foot ulceration and a prerequisite to the development of Charcot neuroarthropathy (CN), which are both recognized as late complications of DSPN. The late complications also drive amputation risk and economic costs of diabetic neuropathy and are also predictors of mortality. DSPN is also a major contributor to falls and fractures.[4,5]

Due to lack of treatments that target the underlying nerve damage, prevention is the key component of diabetes care. Prevention of diabetic neuropathies focuses on glucose control and lifestyle modifications, which includes dietary modifications and exercise.[4] Optimal glucose control is considered the cornerstone for the treatment of diabetes and its complications. Intensive glucose control has been shown to prevent the development of peripheral neuropathy. For patients with diabetic neuropathy, foot care is important to prevent ulceration, infection, and amputation.[5]

There are several pharmacological options for DPN. The American Diabetes Association (ADA), American Academy of Neurology (AAN), and American Academy of Family Physicians (AAFP) recommend use of pregabalin and duloxetine as first line therapy for painful diabetic neuropathy.[3-5] AAFP recommends gabapentin as the first-line alternative.[3] Other treatment options include antidepressants (e.g., amitriptyline, nortriptyline, desipramine, imipramine, venlafaxine), anticonvulsants (e.g. gabapentin, sodium valproate), and capsaicin cream.[3-5] Tramadol has been shown to be effective in the treatment of DPN. Although tramadol has a lower potential for abuse compared with other opioids, given the safety concern, it is not recommended as first or second line treatment.[4]

REFERENCES

1. Lyrica CR prescribing information. Pfizer, Inc. October 2017.
2. Lyrica prescribing information. Pfizer/Parke-Davis. December 2016.
3. Snyder, Matthew J, DO, et al. Treating Painful Diabetic Peripheral Neuropathy: An Update. *American Family Physicians*. 2016; 94 (3):227-234.
4. Pop-Busui, Rodica, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. *Diabetes Care*. 2017; 40: 136-154.
5. Feldman, Eva L., MD, PhD, et al. Treatment of diabetic neuropathy. UpToDate. Last Updated November 2018.

Lyrica CR Prior Authorization with Quantity Limit

TARGET AGENT
Lyrica CR (pregabalin ER)

Prior Authorization and Quantity Limit Target

Agent	GPI	Multisource Code	Quantity Limit per day
Lyrica CR (pregabalin ER)			
82.5 mg tablet	62540060007520	M, N, O, or Y	1 tablet
165 mg tablet	62540060007530	M, N, O, or Y	1 tablet
330 mg tablet	62540060007540	M, N, O, or Y	2 tablets

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
TARGET AGENT will be approved when ALL of the following are met:

1. The patient has ONE of the following diagnosis:
    a. Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
    OR
    b. Postherpetic neuralgia (PHN)

    AND
2. ONE of the following:
    a. The patient has tried and had an inadequate response to ONE of the following generic agents: duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL prerequisite agents

    AND
3. ONE of the following:
    a. The patient has tried and had an inadequate response to pregabalin immediate release
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to pregabalin immediate release that is not expected to occur with the requested agent

    AND
4. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
    AND
5. ONE of the following:
    a. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    b. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    c. ALL of the following:

i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) is greater than the maximum FDA labeled dose
AND
iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Step Therapy Supplement

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx formularies.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT
OBJECTIVE
The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL
The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    a. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

    OR
2. The patient's medication history include the required prerequisite/preferred agent(s) as indicated by:
    a. Evidence of a paid claim(s) within the past 999 days
    OR
    b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event

    OR
3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: As per program specific criteria