Pharmacy Policy Bulletin

Title: Pregabalin (Lyrica®)
Policy #: Rx.01.74

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**

Pregabalin (Lyrica®) is indicated for the treatment of postherpetic neuralgia (PHN), diabetic peripheral neuropathic pain (DPNP), fibromyalgia, and as an add-on therapy for the treatment of partial onset epileptic seizures in adults.

The use of pregabalin (Lyrica®) requires prior authorization (i.e. clinical pharmacist and/or Medical Director review).

**Description:**

Pregabalin's (Lyrica®) exact mechanism of action is unknown. Preclinical studies have shown that pregabalin (Lyrica®) binds with high affinity to the alpha-2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. These results suggest that binding to the alpha-2-delta subunit may be involved in pregabalin's (Lyrica's®) antinociceptive and antiseizure effects.

In vitro, pregabalin (Lyrica®) reduces the calcium-dependent release of several neurotransmitters, possibly by modulation of calcium channel function. Pregabalin (Lyrica®) does not block sodium channels, is not active at opiate receptors, and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake.

**Black Box Warning:**

None

**Policy:**

Pregabalin (Lyrica®) is approved when one of the following inclusion criteria is met:

1. Documentation of diabetic peripheral neuropathic pain
2. Documentation of add-on therapy for partial onset epileptic seizures in adults with documentation of inadequate response or inability to tolerate gabapentin
3. Documentation of diagnosis of post-herpetic neuralgia with documentation of inadequate
response or inability to tolerate gabapentin

4. Documentation of diagnosis of fibromyalgia
5. Documentation of diagnosis of neuropathic pain associated with spinal cord injury

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


Micromedex website [Lyrica]. Available at
Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Lyrica</td>
<td>pregabalin</td>
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Cross References:

Policy Version Number: 3.00
P&T Approval Date: October 10, 2013
Policy Effective Date: December 01, 2013
Next Required Review Date: October 10, 2014

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