

Policies Repository



Policy Title Pregabalin (Lyrica®)

Policy Number FS.CLIN.38

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy **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 (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Pregabalin's (Lyrica®) exact mechanism of action of 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.

Policy Guideline Inclusion

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

- Documentation of neuropathic pain that is associated with diabetic peripheral neuropathy (DPN) secondary to diabetes
- Documentation of add-on therapy for partial onset epileptic seizures in adults with trial and failure or contraindication/intolerance/allergy to gabapentin
- Documentation of diagnosis of postherpetic neuralgia with trial and failure or contraindication/intolerance/allergy to gabapentin
- Documentation of diagnosis of fibromyalgia
- Documentation of diagnosis of non-diabetic neuropathic pain with trial and failure or

contraindication/intolerance/allergy to gabapentin and any three of the following medications:

- An opioid containing product
- Tramadol
- A tricyclic antidepressant
- A lidocaine-containing product
- Carbamazepine
- A venlafaxine-containing product

Policy Guideline Exclusion

Pregabalin (Lyrica®) is denied when **all** of the following exclusion criteria are present:

- No documentation of diagnosis of non-diabetic neuropathic pain with trial and failure or contraindication/intolerance/allergy to gabapentin and any three of the following medications
 - An opioid containing product
 - Tramadol
 - A tricyclic antidepressant
 - A lidocaine-containing product
 - Carbamazepine
 - A venlafaxine-containing product
- No documentation of neuropathic pain that is associated with DPN secondary of diabetes
- No documentation of add-on therapy for partial onset epileptic seizures in adults with trial and failure or contraindication/intolerance/allergy to gabapentin
- No documentation of diagnosis of postherpetic neuralgia with trial and failure or contraindication/intolerance/allergy to gabapentin
- No documentation of fibromyalgia

Policy List of Applicable Drugs

Brand Name	Generic Name
Lyrica	pregabalin

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Beydoun A, Uthman BM, Kugler AR, et al. Safety and efficacy of two pregabalin regimens for add-on treatment of partial epilepsy. *Neurology*. 2005;64(3):475-480.

Dworkin RH, Corbin AE, Young JP JR, et al. Pregabalin for the treatment of postherpetic neuralgia: a randomized, placebo-controlled trial. *Neurology*. 2003;60(8):1274-1283.

Dworkin RH, Backonja M, Rowbotham MC, et al. Advances in neuropathic pain diagnosis, mechanisms, and treatment recommendations. *Arch Neurol*. 2003;60:1524-1534.

Dworkin RH, O'Connor AB, Backonja M, et al. Pharmacologic management of neuropathic pain: Evidenced-based recommendations. *Pain*. 2007; 132:237-251.

Freyenhagen R, Strojek K, Griesing T, Whalen E, Balkenohl M. Efficacy of pregabalin in neuropathic pain evaluated in a 12-week, randomized, double-blind, multicentre, placebo-controlled trial of flexible- and fixed-dose regimens. *Pain*. 2005;115(3):254-263.

Lesser H, Sharma U, LaMoreaux L, Poole RM. Pregabalin relieves symptoms of painful diabetic neuropathy: a randomized controlled. *Neurology*. 2004;63(11):2104-2110.

Lyrica® (pregabalin hydrochloride) [package insert]. New York, NY: Pfizer, Inc.; April 2009.

McDonald AA, Portenoy RK. How to use antidepressants and anticonvulsants as adjuvant analgesics in the treatment of neuropathic cancer pain. *J Support Oncol*. 2009;4:43-52.

Oregon Health & Science University. Antiepileptics: Drug Effectiveness review project. [Oregon Health & Science University Web site]. Available at: <http://www.ohsu.edu>. Accessed April 4, 2008.

Sindrup SH, Bach FW, Madsen C, et al. Venlafaxine versus imipramine in painful polyneuropathy a randomized controlled trial. *Neurology*. 2003;60:1284-1289.

United States Department of Veterans Affairs. Pregabalin monograph. [United States Department of Veterans Affairs Web site]. Available at: <http://www.pbm.va.gov>. Accessed April 4, 2008.

Policy Link to Related Policies

Printed

07/06/2009 10:23:47

The Policy Bulletins on this web site were developed to assist AmeriHealth and its subsidiaries ("AmeriHealth") in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an AmeriHealth member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. AmeriHealth does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of AmeriHealth. If you have a specific medical condition, please consult with your doctor. AmeriHealth reserves the right at any time to change or update its Policy Bulletins. ©2008 AmeriHealth, Inc. All Rights Reserved. Current Procedural Terminology ©2008 American Medical Association. All Rights Reserved.