



MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS
NEXT REVIEW DATE: 3RD QTR 2012

ORIGINAL EFFECTIVE DATE: 2/1/11
LAST REVIEW DATE: 9/29/11
LAST CRITERIA REVISION DATE: 4/26/11
ARCHIVE DATE:

Lyrica ® (pregabalin)

2-1-2011

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety. The guideline is not a guarantee of coverage.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational & thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available. The guideline in effect on the date of service will determine coverage.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Although the mechanism of how Lyrica (pregabalin) works is not completely known, information for this product from the manufacturer suggests that this agent binds with a certain site in central nervous system tissue and therefore blocks certain neurotransmitters in the spinal cord along with other proposed actions on other neurological pathways originating from the brainstem. Lyrica (pregabalin) is chemically similar to gabapentin (Neurontin®) and Neurontin® is commercially available as a generic medication.

Precertification:

Precertification* for Lyrica is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail and mail order prescription benefit. Medications requiring precertification are identified on the following list located on the Internet at <http://www.azblue.com/pdfs/medications/pharmacy/QIList.pdf>

"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions"

This list may also be requested by calling (602) 864-4273 or (800) 232-2345, ext. 4273.

Please refer to this list for other Lyrica prescription claim limitations where applicable.



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* Precertification will not be required for certain individuals who are already receiving Lyrica. Members having at least one BCBSAZ paid claim for Lyrica within the three months preceding the initial effective date of this guideline will not need to obtain precertification.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

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Criteria:

- FDA-approved dosage of Lyrica is considered *medically necessary* for treatment of the indications below:

In adult members (> 16 years of age) with documented diagnosis of the conditions below:

- Adjunctive therapy for patients with partial onset seizures
- Neuropathic pain associated with diabetic peripheral neuropathy
- Post-herpetic neuralgia
- Fibromyalgia
- Other neuropathic pain conditions, defined by the US National Guideline Clearinghouse (as pain initiated or caused by a primary lesion or dysfunction in the nervous system and is characterized by spontaneous pain described as lancinating, paroxysmal, burning, constant, cramping; and evoked pain of dysethesia, allodynia, hyperalgia, or hyperpathia), for which statistically significant US clinical medical evidence has established the safety and efficacy for the use of Lyrica and;
 - Therapy to treat the disease causing the neuropathic pain has been initiated, when applicable

And (all when applicable)

1. Member does not have a known hypersensitivity to pregabalin or any of its components.
2. Member does not have an actively diagnosed myopathy or markedly elevated creatine kinase levels.

Lyrica for all other indications not previously listed, including acute pain, somatic pain from strains or sprains, low back pain without radiculopathy, tendonitis, repetitive strain without evidence of entrapment neuropathy, other forms of non-neuropathic pain, monotherapy for partial onset seizures, and treatment of pediatric members, is considered experimental or investigational based upon;

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than established alternatives



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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Pharmacy and Therapeutics review	1-12-2011	Adopted guideline
Director Pharmacy Mgmt review	1/12/2011	Development

Criteria Revisions:



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Resources:

Lyrica package insert review on 12-27-2010
Mayo Clin Proc. March 2010;85(3)(suppl):S3-S14
US National Guideline Clearinghouse Guideline Summary; Antiepileptic drugs guideline for chronic pain, NGC-4707 12-27-2010
US National Guideline Clearinghouse Guideline Summary; Pharmacologic management of neuropathic pain: evidence-based recommendations, NGC-6049 12-27-2010
US National Guideline Clearinghouse Guideline Summary; EFNS guidelines on pharmacological treatment of neuropathic pain, NGC-5495 12-27-2010
Pain Res Manage Vol 12 No 1 Spring 2007 pps 13-21
