

Pharmacy Policy Bulletin

Category:	Managed Rx Coverage
Number:	J-300
Subject:	Lyrica (pregabalin)
Effective Date Begin:	December 3, 2008
Effective Date End:	
Original Date:	December 7, 2005
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Policy Applies to: *Commercial and Medicare plans*

Background:

Pregabalin (Lyrica™) is an analog of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), exhibits analgesic, anxiolytic and anticonvulsant activity. It is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). It is also indicated for adjunctive treatment of adult patients with partial onset seizures and for the treatment of fibromyalgia. It is not indicated as monotherapy for partial onset seizures. Unlike other medications used for these indications, pregabalin is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake. Pregabalin is the first drug approved for use in the treatment of fibromyalgia.

The literature does not support the use of pregabalin for the treatment of generalized anxiety disorder and will not be covered to treat this condition.

Approval Criteria: When a benefit, coverage for pregabalin will be approved if members meet one of the following criteria:

1. The member has at least one claim for a medication used for the treatment of diabetes within the last year, **OR**
2. There is a claim for one antiviral medication used for the treatment of herpes zoster infection in the members' pharmacy profile within the last year, **OR**
3. There are claims for two antiepileptic drugs (AED) in the members' pharmacy profile within the last year, **OR**
4. There are claims for two tricyclic antidepressants (TCA) in the members' pharmacy profile within the last year, **OR**
5. There are claims for one AED and one TCA in the members' pharmacy profile within the last year.

Members who meet the criteria as outlined above will receive automatic authorization at the pharmacy without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required.

Members who do not meet this above criteria will require prior authorization. One of the following criteria would then need to be documented.

1. The member has a documented diagnosis of DPN, **OR**
2. The member has a documented diagnosis of PHN, **OR**
3. The member has a documented diagnosis of seizures: **AND** has tried and failed two AED, **OR**
4. The member has a documented diagnosis of unspecified neuropathic pain: **AND** has failed two other medications in the following classes: AED or TCA. **OR**
5. The member has a documented diagnosis of fibromyalgia as determined by clinical notes including, but not limited to, confirmation of widespread bilateral pain both above and below the waist for > 3 months duration **AND** the presence of at least 11 of 18 specific tender points **AND** documented fibromyalgia-related symptoms (e.g. fatigue, sleep disturbance, neurologic symptoms, and/or exercise intolerance). **AND**
6. The member has a documented trial and failure of at least one additional agent used to treat fibromyalgia (e.g. tricyclic agents, cyclobenzaprine, SSRIs, tramadol).

Authorization Duration

If approved, up to a lifetime authorization may be granted.

References:

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4. French JA, Kugler AR, Robbins JL, et al. Dose-response trial of pregabalin adjunctive therapy in patients with partial seizures. *Neurology*. 2003;60:1631-1637.
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8. Finnerup NB, Otto M, McQuay HJ, et al. Algorithm for neuropathic pain treatment: An evidence based proposal. *Pain*. 2005; 1-17.
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11. Wolfe F, et al. The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia: Report of the Multicenter Criteria Committee. *Arthritis and Rheumatism*. 1990;33(2): 160-72.
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