

Statement on Coverage of Pregabalin/Lyrica

Coventry Health Care, Inc.

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Coventry Health Care covers the reimbursement of the drug pregabalin/Lyrica for use in the treatment of fibromyalgia. Our guidelines are based upon current medical literature and include a step therapy approach to the treatment of fibromyalgia that follows current published expert recommendations.

Comprehensive evaluation of the literature dealing with the treatment of fibromyalgia indicates that a wide array of drugs have been clinically investigated and are currently in use and recommended by experts in the field. Pregabalin is the only drug that has undergone application for FDA approval for an indication of fibromyalgia. The granting of FDA approval, however, does not change its place in the spectrum of available therapy that is currently supported by medical evidence and published expert opinion, nor does it necessarily move the drug to a first line recommendation.

Pregabalin has been approved by the FDA for use as a therapeutic agent for fibromyalgia on the basis of a study that showed improvement in selected clinical measures that was statistically greater than improvement seen with administration of placebo. This study did not address the efficacy of pregabalin in comparison to any other treatment standards, including accepted fibromyalgia treatment drugs and modalities such as:

- One of the tricyclic antidepressants
- Muscle relaxants such as cyclobenzaprine
- Non medicinal therapy such as cognitive behavior therapy
- Exercise therapy
- Addition of a Selective Serotonin Reuptake Inhibitor/SSRI (eg, fluoxetine)

Any drug therapy considered for the treatment of fibromyalgia must be considered in light of its known benefits versus its potential risks.

In addition, as of Jan. 31, 2008, pregabalin labeling must include a Black Box Warning based on the FDA's conclusion that patients taking pregabalin historically have had approximately twice the risk of suicidal behavior or ideation as compared to patients taking placebo.

[See significant medical literature reference list attached]

Note: Physicians seeking more information can visit <http://patients.uptodate.com> and search for "Treatment of Fibromyalgia in Adults."