

**DRUG APPROVAL** **Lyrica<sup>®</sup> (pregabalin)**

Lyrica<sup>®</sup> (pregabalin, Pfizer Inc.) was approved in December 2004 by the U.S. Food and Drug Administration (FDA) for the management of postherpetic neuralgia (PHN) and neuropathic pain associated with diabetic peripheral neuropathy (DPN).<sup>1,2</sup> Lyrica is the first FDA-approved treatment indicated for both DPN and PHN.<sup>2</sup> On June 13, 2005, Pfizer Inc. announced Lyrica had been approved as adjunctive therapy for adults with partial onset seizures.<sup>1,3</sup> Adverse effects with Lyrica therapy may include dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, or difficulties with concentration/attention.<sup>1</sup> The FDA has classified Lyrica as a Schedule V controlled substance.<sup>1</sup> Lyrica is available as 25-mg, 50-mg, 75-mg, 100-mg, 150-mg, 200-mg, 225-mg, and 300-mg capsules.<sup>1</sup>

**BACKGROUND** **Diabetic Peripheral Neuropathy (DPN)**

DPN is a nerve disorder caused by damage to nerves from diabetes.<sup>4,5</sup> It is estimated that half of those with diabetes will have some form of peripheral neuropathy.<sup>5</sup> Nearly 15% of people with diabetes experience nerve pain at any given time. Symptoms of DPN may include tingling, burning, sharp or stabbing pain, or prickling sensations; numbness; heightened sensitivity to touch; inability to feel pain and temperature as well; muscle weakness, and loss of reflexes which can lead to changes in how a person walks; and loss of balance and coordination.<sup>5</sup> The symptoms of DPN are often worse at night.<sup>5</sup>

**Postherpetic Neuralgia (PHN)**

PHN is chronic nerve pain caused by damage to nerves from shingles (herpes zoster), a painful rash that forms blisters on the skin.<sup>6</sup> Each year approximately one million individuals in the United States develop shingles and close to 20% of them develop PHN.<sup>6</sup> The symptoms of PHN may include sharp, burning, throbbing, or stabbing pain that occurs all the time or some of the time.<sup>6</sup> Patients with PHN may be overly sensitive to touch and changes in temperature.<sup>6</sup>

**DOSAGE AND ADMINISTRATION**

Lyrica is an oral medication that is given without regard to food.<sup>1</sup> When discontinuing Lyrica therapy, it should be gradually tapered over a minimum of one week.<sup>1</sup>

**Neuropathic Pain Associated with Diabetic Peripheral Neuropathy<sup>1</sup>**

The maximum recommended dose of Lyrica is 100 mg three times daily (300 mg/day) in patients with a creatinine clearance (CrCl) of at least 60 mL/min. Dosing should begin at 50 mg three times a day and may be increased to 300 mg/day within one week based on efficacy and tolerability. Treatment with doses above 300 mg/day is not recommended.

**Postherpetic Neuralgia<sup>1</sup>**

The recommended dose of Lyrica is 75 mg to 150 mg twice daily, or 50 mg to 100 mg three times daily (150 mg to 300 mg/day) in patients with a CrCl of at least 60 mL/min. Dosing should begin at 75 mg two times a day, or 50 mg three times a day (150 mg/day) and may be increased to 300 mg/day within one week based on efficacy and tolerability. See full prescribing information for details regarding the appropriate dosing in those patients who do not experience sufficient pain relief after two to four weeks of Lyrica therapy.

## **PLACE IN THERAPY** Diabetic Peripheral Neuropathy (DPN)<sup>7</sup>

According to the American Diabetes Association (ADA), anticonvulsants (e.g., Lyrica, gabapentin, topiramate) are suggested as a second-line alternative to tricyclic antidepressants (e.g., amitriptyline, imipramine) in the treatment of symptomatic neuropathy. Certain medications may be used in combination (e.g., an antidepressant and an anticonvulsant), or combined with topical or nonpharmacological therapies, in cases of severe pain.

## **Postherpetic Neuralgia (PHN)<sup>8</sup>**

The American Academy of Neurology (AAN) supports the use of Lyrica for PHN as it has medium-to-high efficacy and a low level of side effects.

## **CAREMARK RESPONSE**

Based on currently available data, Caremark recommends for your consideration and at your discretion, coverage of Lyrica when your prescription benefit plan also covers other anticonvulsants for the treatment of DPN and PHN.

Clinical programs are available for Lyrica that focus on managing appropriate utilization. Please contact your Caremark account representative for further details.

Caremark will continue to monitor the use of Lyrica to determine if any additional clinical programs are needed.

## **CAREMARK CONTACT**

For more information, please contact your Caremark account representative.

*Please Note: This document provides a brief overview of the subject. Please refer to the manufacturer's full prescribing information for a complete discussion of the product. This review is provided as a reference only, and is based in part on information derived from third parties.*

## **References**

1. Lyrica<sup>®</sup> product information. Pfizer Inc., July 2005.
2. Pfizer Inc. Lyrica Web Site. Press Release: FDA Approves Pfizer's Lyrica<sup>™</sup> for the Treatment of the Two Most Common Forms of Neuropathic (Nerve) Pain. Available at: <https://www.lyrica.com/pdf/USApprovalRelease.pdf>. Accessed April 22, 2005.
3. Pfizer Inc. Lyrica Web Site. Press Release: FDA Approves Pfizer's Lyrica<sup>™</sup> as Epilepsy Add-On Treatment for Partial Onset Seizures. Available at: [https://www.lyrica.com/pdf/USApprovalRelease\\_Epilepsy.pdf](https://www.lyrica.com/pdf/USApprovalRelease_Epilepsy.pdf). Accessed June 13, 2005.
4. National Institutes of Health. National Institute of Neurological Disorders and Stroke: NINDS Diabetic Neuropathy Information page. Available at: <http://www.ninds.nih.gov/disorders/diabetic/diabetic.htm>. Accessed May 5, 2005.
5. American Diabetes Association. Diabetic Neuropathies: A statement by the American Diabetes Association. *Diabetes Care* [serial online]. 2005; 28(4):956-962. Available at: <http://care.diabetesjournals.org/cgi/reprint/28/4/956.pdf>. Accessed August 25, 2005.
6. VZV Research Foundation. Post-Herpetic Neuralgia. Available at: <http://www.vzvfoundation.org/phn.html>. Accessed May 5, 2005.
7. National Institutes of Health. National Institute of Diabetes and Digestive and Kidney Diseases. Diabetic Neuropathies: The Nerve Damage of Diabetes. Available at: <http://diabetes.niddk.nih.gov/dm/pubs/neuropathies/index.htm>. Accessed May 5, 2005.
8. American Academy of Neurology. Treatment of Postherpetic Neuralgia: AAN Evidence-Based Guideline Summary for Clinicians. Available at: [http://www.aan.com/professionals/practice/pdfs/pn\\_guideline\\_physicians.pdf](http://www.aan.com/professionals/practice/pdfs/pn_guideline_physicians.pdf). Accessed May 5, 2005.