

Case Number:	CM14-0117267		
Date Assigned:	08/06/2014	Date of Injury:	01/09/2007
Decision Date:	09/24/2014	UR Denial Date:	06/27/2014
Priority:	Standard	Application Received:	07/25/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 60 year old woman who was injured at work on 1/9/2007. The injury was primarily to her neck, back and extremities. She is requesting review of denial for Lyrica Capsules 25mg # 120. The medical records corroborate ongoing care for her injuries. The Primary Treating Physician's Progress Reports (PR-2s) are provided and indicate that her diagnoses include: Cervical Injury with Disc Annular and Facet Tears; Cervical Radiculopathy; Thoracic Disc Herniation; Left Sacroiliac Joint Injury. She has been treated with Percocet, Nucynta, and was prescribed Lyrica 25 mg (two tablets BID).

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Lyrica CAP 25mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22.

Decision rationale: The CA/MTUS Chronic Pain Medical Treatment Guidelines comment on the use of anti-epilepsy drugs (AEDs) such as Lyrica. These guidelines state that AEDs are recommended for neuropathic pain (pain due to nerve damage. (Gilron, 2006) (Wolfe, 2004)

(Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions.

Outcome: A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Specifically studied disease states include:

Painful polyneuropathy: AEDs are recommended on a trial basis (gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example). The other first-line options are a tri-cyclic antidepressant (if tolerated by the patient), or a SNRI antidepressant (such as duloxetine).

Postherpetic neuralgia: Gabapentin and Pregabalin are recommended. Central pain: There are so few trials (with such small sample size) that treatment is generally based on that recommended for peripheral neuropathy, with gabapentin and pregabalin recommended. Lamotrigine has been found to be effective for central post-stroke pain (see below for specific drugs), and gabapentin has also been found to be effective. Specific information on Lyrica is provided in the guidelines and states the following: Pregabalin (Lyrica, no generic available) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of Pregabalin as the first approved treatment for fibromyalgia. Dose adjustment is necessary in patients with renal insufficiency. The antiepileptic agents gabapentin and Pregabalin have attained widespread usage in the treatment of painful diabetic peripheral neuropathy (DPN). This pooled analysis of 7 randomized controlled trials comparing different doses and frequencies of Pregabalin for painful DPN concluded that Pregabalin at doses of 150, 300, and 600 mg daily is associated with dose-related relief of pain and reduction in sleep interference in patients with painful DPN. (Freeman, 2008) Side-Effect Profile: Pregabalin has been associated with many side effects including edema, CNS depression, weight gain, and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. It has been suggested that this drug be avoided if the patient has a problem with weight gain. (Jensen, 2006) Dosing Information: Diabetic neuropathy -- Begin with 50 mg 3 times a day; may be increased in one week based on tolerability and effect to a maximum of 300 mg/day. (Doses up to 600 mg/day were evaluated with no additional benefit and increase in side effects.) Postherpetic neuralgia - Begin with 50 mg three times a day for one week; may be increased to 100 mg three times a day after one week based on tolerability and effect. Dose may

be increased as tolerated after two to four weeks up to 300 mg twice daily (maximum dose 600 mg/day). Trial period: There is no established trial period, but the onset of action is thought to be less than 1 week. (Attal, 2006) Weaning: Do not discontinue pregabalin abruptly and weaning should occur over a one-week period. Withdrawal effects have been reported after abrupt discontinuation. In this case, the provider suggests that the use of Lyrica is for the treatment of cervical radiculopathy. There is insufficient documentation in support of an ongoing assessment of the efficacy of Lyrica in addressing the patient's symptoms. Specifically, as stated in the guidelines "there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use." Further, "the continued use of AEDs depends on improved outcomes versus tolerability of adverse effects." Finally, there is insufficient documentation of a titration plan for this medication. For these reasons, the use of Lyrica is not considered as medically necessary.