

Case Number:	CM15-0059262		
Date Assigned:	04/03/2015	Date of Injury:	11/14/2001
Decision Date:	05/06/2015	UR Denial Date:	03/07/2015
Priority:	Standard	Application Received:	03/30/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: District of Columbia, Virginia
Certification(s)/Specialty: Internal Medicine

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 39 year old female, who sustained an industrial injury on November 14, 2001. She has reported back pain, shoulder pain, knee pain, and leg pain. Diagnoses have included chronic regional pain syndrome and lumbago. Treatment to date has included medications, use of a walker, intrathecal pump, left knee surgery, stellate ganglion block, sympathetic block, physical therapy, spinal cord stimulator, and diagnostic testing. A progress note dated February 20, 2015 indicates a chief complaint of left leg pain and left flank and abdominal pain radiating to the pelvis. The treating physician documented a plan of care that included medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

LYRICA (PREGABALIN) 225 MG #90 WITH 2 REFILLS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines ANTI-EPILEPSY.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 16-20.

Decision rationale: Per MTUS: 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. (Blommel, 2007) 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. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) 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. (Tassone, 2007) (Attal, 2006) 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). (ICSI, 2007) 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. This patient had chronic pain issues and .per review of the clinical documentation provided, there was no evidence that this patient had diabetic neuropathy or post herpetic neuralgia, clear indications for which to prescribe this medication as per MTUS guidelines. Furthermore, this patient had been on this medication for several months and did not appear to have a functional benefit from this medication. For the reasons stated above, this medication is not medically necessary for this patient.