MAXIMUS Federal Services

Case Number:	CM14-0203425		
Date Assigned:	12/15/2014	Date of Injury:	09/30/1999
Decision Date:	02/04/2015	UR Denial Date:	11/12/2014
Priority:	Standard	Application Received:	12/05/2014

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 Occupational 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 46-year-old female, with a reported date of injury of 09/30/1999. The result of the injury was low back pain.The current diagnoses include chronic pain syndrome, lumbar post-laminectomy syndrome at L4-S1, and lumbosacral neuritis.The past diagnoses include lumbar post-laminectomy syndrome at L4-S1, and lumbosacral neuritis.Treatments have included Lyrica 150mg; Tramadol HCL 50mg; Savella 50mg; Ibuprofen 800mg; Cymbalta 30mg; acupuncture; epidural steroid injection; massage therapy; physical therapy; nerve stimulator; computerized tomography (CT) scan of the lumbar spine on 10/23/2002, 03/03/2008, and 02/20/2012; x-ray of the lumbar spine on 06/08/2009 and 09/13/2011; MRI of the lumbar spine on 04/15/2002 and 08/09/2010; and CT discogram of the lumbar spine on 06/15/2000. The medical records provided for review do not include the diagnostic study reports.The medical report dated 11/04/2014 indicates that the injured worker had slightly decreased pain in her left buttocks, left, and foot since the last visit. She reported a 50% benefit from the use of Lyrica, and said that the medication helped her fall asleep at night. The injured worker continued to have family members help her with cooking, household chores, and childcare. She was able to bathe/shower and dress herself without assistance. She could walk for up to 15-20 minutes without pain. The injured worker rated her low back pain an 8 out of 10, and described it as aching, sharp, shooting, spasms. She rated the pain in her left buttock and right leg a 7 out of 10. An examination of the lumbar spine showed tenderness to palpation over the right lumbar facets, left lumbar facets, right paravertebral lumbar spasm, right sacroiliac joint, and left sacroiliac joint; positive straight leg raise on the right at 70 degrees and on the left at 50 degrees; a compensated gait; normal muscle tone; right and left lateral flexion at 10 degrees; flexion at 30 degrees; pain with forward flexion; and pain with extension. The treating physician recommended Savella to help increase the injured worker's level of activity.On 11/12/2014,

Utilization Review (UR) denied the request for Savella 50mg #60. The UR physician noted that there was little or no evidence that the cause of fibromyalgia is related to industrial injuries. The Chronic Pain Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription of Savella 50mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Milacipran (Ixel) Page(s): 62-63. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Milnacipran (Savella Â®)

Decision rationale: The MTUS Guidelines do not recommend the use of milacipran. Milacipran is under study as a treatment for fibromyalgia syndrome. The Food and Drug Administration (FDA) Phase III study demonstrated "significant therapeutic effects" of milnacipran for treatment of fibromyalgia syndrome. Milnacipran has been approved for the treatment of depression outside of the U.S. and is in a new class of antidepressants known as Norepinephrine Serotonin Reuptake Inhibitors (or NSRIs). What makes Milnacipran different from the Selective Serotonin Reuptake Inhibitors (SSRIs) - drugs like Prozac - and Selective Norepinephrine Reuptake Inhibitors (SNRIs) - drugs like Effexor - is that Milnacipran affects two neurotransmitters, norepinephrine and serotonin. The Official Disability Guidelines (ODG) reports that the FDA has now approved milnacipran (Savella) for the management of fibromyalgia. Milnacipran should be prescribed with caution in patients with a history of seizure disorder, mania, or controlled narrow-angle glaucoma and should ordinarily not be prescribed in patients with substantial alcohol use or evidence of chronic liver disease. As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan. In this case, the injured worker is not reported to be suffering from fibromyalgia from an industrial cause. Savella is not recommended as an adjunct pain medication related to lumbosacral neuritis. Therefore, this request for 1 prescription of Savella 50mg #60 is not medically necessary.