

Case Number:	CM13-0040401		
Date Assigned:	12/20/2013	Date of Injury:	06/10/2008
Decision Date:	03/17/2014	UR Denial Date:	10/01/2013
Priority:	Standard	Application Received:	10/29/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Neurology, has a subspecialty in Neuromuscular 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 physician 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 claimant sustained a work-related injury on June 10, 2008. She subsequently developed a chronic pain syndrome, myalgia, depression and myositis. According to a progress note dated on September 9, 2013, the patient was documented to have multifocal chronic pain, fatigue, back pain, legs fingers and hips pain. Her neurologic examination was normal. The patient was treated with pain medications, topical compound, medical food and psychological consultation. The provider requested authorization to continue using Savella and topical medication containing tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

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) Pain (Chronic), Milnacipran (Savella®).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Improvement, and the online source: www.frx.com/pi/Savella_pi.pdf.

Decision rationale: Milnacipran (Savella) is a serotonin-norepinephrine reuptake inhibitor (SNRI) used in the clinical treatment of fibromyalgia. According to the Official Disability

Guidelines (ODG), Savella is under study as a treatment for fibromyalgia syndrome. An 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 a dual serotonin- and norepinephrine-reuptake inhibitor (SNRI). (Rooks, 2007) Milnacipran, one of the pioneer serotonin and norepinephrine reuptake inhibitors (SNRIs), was designed from theoretic considerations to be more effective than selective serotonin reuptake inhibitors (SSRIs) and better tolerated than tricyclic antidepressants (TCAs). (Kasper, 2010). 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. (FDA, 2009) 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. Based on the medical records provided for review there is no clinical evidence that the patient suffered from fibromyalgia. Furthermore there is no objective documentation of the efficacy of previous use of the medication. The request for Savella 50mg #60 is not medically necessary and appropriate.