

<b>Case Number:</b>	CM14-0198879		
<b>Date Assigned:</b>	12/09/2014	<b>Date of Injury:</b>	04/10/2004
<b>Decision Date:</b>	01/22/2015	<b>UR Denial Date:</b>	10/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/26/2014

### 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 Neurology, has a subspecialty in Neuromuscular Medicine and is licensed to practice in New Jersey. 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 64 year-old female, who was injured on April 10, 2004, while performing regular work duties. The mechanism of injury is due to a trip and fall, resulting in injury of the left knee, left hip, left shoulder, left elbow, and left side of the head. The records indicate treatments received by the injured worker include medications, bracing, chiropractic sessions, physical therapy, left knee surgery, medical branch blocks, aquatic therapy, and trigger point injections. The agreed medical evaluation on April 29, 2013, indicates the injured worker was seen by [REDACTED] on July 7, 2005, indicates a diagnosis of fibromyalgia syndrome, and was treated with light duty restrictions, and physical therapy for the neck and lower back. However, the agreed medical evaluator on October 26, 2009, indicates that the injured worker does not have fibromyalgia, and indicates a diagnosis of myofascial pain syndrome. The records indicate the injured worker had been seen by [REDACTED] on March 14, 2006, and a diagnosis of fibromyalgia superimposed on chronic cervicothoracic and lumbar strains were given. On September 13, 2007, the injured worker underwent left shoulder surgery. The records of June 10, 2014, indicate there are "several trigger points throughout the back consistent with FMS"; however they do not indicate what the trigger points are, or how they are consistent with FMS. The records do indicate a change of sleep apnea and a sleep study is recommended. The records do indicate the injured worker experiences numbness, pricking, and burning sensations. The records do not indicate failure of oral medications. The request for authorization is for Trazodone HCL 50mg, quantity #30 with four (4) refills; Lidoderm patch 5%, quantity #90 with 2 refills; and Savella 50mg, quantity #60 with four (4) refills. The primary diagnosis is thoracic or lumbosacral neuritis or radiculitis. Additional diagnoses are: exogenous obesity, and chronic pain syndrome. On October 29, 2014, Utilization Review provided a modified certification of Trazodone 50mg, quantity #30 with no refills; and non-certified the request for Lidoderm patch

5%, quantity #90 with 2 refills; and Savella 50mg, quantity #60 with four (4) refills, based on MTUS, Chronic Pain Medical Treatment, and ODG guidelines.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Trazodone HCL 50 MG #30 with 4 Refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Schwartz, T., et al. (2004). ""A comparison of the effectiveness of two hypnotic agents for the treatment of insomnia"." Int J Psychiatr Nurs Res 10(1): 1146-1150

**Decision rationale:** There is no clear evidence that the patient was diagnosed with major depression requiring Trazodone. There is no formal psychiatric evaluation documenting the diagnosis of depression requiring treatment with Trazodone. In addition, there is no recent documentation of insomnia. There is no documentation of failure of first line treatments for insomnia and depression. Therefore, the request for Trazodone HCL 50 MG #30 with 4 refills is not medically necessary.

**Lidoderm Patch 5 Percent #90 with 2 Refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 56.

**Decision rationale:** According to MTUS guidelines, Lidoderm is the brand name for a lidocaine patch produced by [REDACTED]. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin. In this case, there is no documentation that the patient developed neuropathic pain that did not respond to first line therapy and the need for Lidoderm patch is unclear. There is no documentation of efficacy of previous use of Lidoderm patch. Therefore, the prescription of Lidoderm Patch 5 Percent #90 with 2 refills is not medically necessary.

**Savella 50 MG #60 with 4 Refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) (ODG) Pain (Chronic), Milnacipran (Savella®)(<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm> Alignment)

**Decision rationale:** Milnacipran (Savella) is a serotonin-norepinephrine reuptake inhibitor (SNRI) used in the clinical treatment of fibromyalgia. According to ODG guidelines, 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). 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). 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. 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. Therefore, the prescription for Savella 50mg #60 is not medically necessary.