

<b>Case Number:</b>	CM14-0042273		
<b>Date Assigned:</b>	06/30/2014	<b>Date of Injury:</b>	07/25/2003
<b>Decision Date:</b>	08/19/2014	<b>UR Denial Date:</b>	03/28/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/08/2014

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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:

Patient is a 63-year-old female with a 07/25/03 date of injury. Physician's report of 01/15/14 states the following: patient fell, landing on her left side, causing increased low back pain. Physical exam reveals positive foraminal compression test bilaterally, pain in the middle of the lumbar spine and bilateral paraspinal muscles with negative SLR in sitting position, bilaterally. X-ray findings of the lumbar spine reveal adequate hardware implantation, no fractures. Diagnoses include cervical spine discopathy with cephalgia, bilateral shoulder impingement syndrome with acromioclavicular joint arthrosis, s/p bilateral carpal tunnel release, s/p revision surgery at L4-5, bilateral knee patellofemoral syndrome with possible right meniscal injury, bilateral foot and ankle sprain/arthrosis, psychiatric complaints. Rheumatology progress report dated 03/12/2014 states complaints of continued total body pain, chronic fatigue, problems sleeping morning gel phenomenon-minutes, no new joint swelling. Objective findings include EMG negative for 4 extremities, no new joint swelling, normal neurologic examination, no rheumatoid arthritis deformities, tender points of fms. Diagnoses: Myalgia and myositis NOS, postlaminectomy syndrome lumbar, post-proc states NEC. Current request is for Savella 50 mg #60.

### 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 cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment Guidelines, CA MTUS §9792.24.2, Reuptake Inhibitors (SNRIs) – drugs like Effexor® – is that Milnacipran affects two neurotransmitters, norepinephrine and serotonin. (Rooks, 2007)(pages 62-63) and the Non-MTUS (<http://www.drugs.com/pro/savella.html>).

**Decision rationale:** Although MTUS Chronic Pain Medical Treatment Guidelines states that Savella is not FDA approved and not available in the United States, a 2009 announcement by the US food and drug administration states that Savella (a selective serotonin and norepinephrine dual reuptake inhibitor) was approved in the management of fibromyalgia. The previous adverse determination dated 03/28/14 makes a reference to a psychology QME dated 04/10/09 including an axis III diagnoses of a history of multiple somatic complaints previously identified as possible autoimmune disorder versus fibromyalgia. The report noted that outside medical records had established a long history of psychological somatization and that by 1977 the patient was described as having total body pain. That said, the diagnoses listed do not include fibromyalgia, and the records don't specify the diagnosis that is to be addressed with administration of Savella. In addition, the American College of Rheumatology released diagnostic criteria for fibromyalgia, which are listed below: A patient satisfies diagnostic criteria for fibromyalgia if the following 3 conditions are met: 1. Widespread pain index (WPI) and symptom severity (SS) scale score or WPI 3-6 and SS scale score. 2. Symptoms have been present at a similar level for at least 3 months. 3. The patient does not have a disorder that would otherwise explain the pain. The reports do not indicate the patient's ongoing pain index or symptom severity score. The guideline criteria for administration of Savella are not met. Therefore, the request is not medically necessary.

