

<b>Case Number:</b>	CM15-0193682		
<b>Date Assigned:</b>	10/07/2015	<b>Date of Injury:</b>	05/16/2002
<b>Decision Date:</b>	11/18/2015	<b>UR Denial Date:</b>	09/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2015

### 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: California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 61 year old male, who sustained an industrial injury on 05-16-2002. He has reported injury to the neck and right arm. The diagnoses have included cervical degenerative disc disease, status post multiple fusions; failed neck syndrome; cervical facet arthropathy; tinnitus, bruxism, and temporomandibular joint disorder; bilateral hemi-facial spasm; right long, ring, and small finger trigger; and left thumb carpometacarpal joint osteoarthritis. Treatment to date has included medications, diagnostics, injections, and surgical intervention. Medications have included OxyContin, Oxycodone, Suboxone, Clonidine, and Lyrica. A progress note from the treating physician, dated 07-22-2015, documented a follow-up visit with the injured worker. The injured worker reported chronic neck pain and bilateral upper extremity radiculopathy; he drops items with his hands; the right upper extremity is worse than the left; attempts to withdraw have resulted in severe anxiety, sweats, and muscle cramps; he is having difficulty with the reduced dosage of Suboxone; he is having ringing of his right ear since his neck fusion surgery last year; he underwent treatment with Botulinum Toxin injections into his pterygoids with initial significant improvement; he has bilateral hemi-facial spasms; he has pain in the right shoulder with burning sensation; he continues to have headaches; and the Lyrica is helping him with the pain. Objective findings included he is in no apparent acute distress, nor does he show signs of withdrawal; no spasms on touch and palpation at the maxillary portions of the face; exam of the neck reveals posterior and anterior surgical scars; there is pain on flexion and extension of the neck; there is limited extension and rotation; pain can be elicited on deep palpation of the right shoulder; Jamar grip strength is decreased on the right; and sensorium appears intact. The treatment plan has included the request for Savella 50mg, #30 with 2 refills. The original utilization review, dated 09-25-2015, non-certified the request for Savella 50mg, #30 with 2 refills.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Savella 50mg, #30 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, updated 9/8/15: Milnacipran (Savella).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Milnacipran (Ixel). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Milnacipran (Savella®) Section.

**Decision rationale:** The MTUS Guidelines do not recommend the use of milnacipran. Milnacipran 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 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 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, there is no evidence that the injured worker has been diagnosed with fibromyalgia, therefore, the request for Savella 50mg, #30 with 2 refills is determined to not be medically necessary.