

Case Number:	CM15-0162710		
Date Assigned:	08/31/2015	Date of Injury:	01/05/1994
Decision Date:	10/14/2015	UR Denial Date:	08/08/2015
Priority:	Standard	Application Received:	08/19/2015

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: Texas, California

Certification(s)/Specialty: Family Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 63 year old male patient, who sustained an industrial injury on 1-5-94. He reported low back, right lower extremity and right foot injuries after a propane tank rolled onto him and pinned him to the truck. The diagnoses include post lumbar laminectomy syndrome, spinal lumbar degenerative disc disease and lumbar radiculopathy. Per the doctor's note dated 7-24-15, he had complains of low back pain radiating to the right leg, rated 6 out of 10 with medications and 10 out of 10 without medications. He also noted poor sleep quality. He noted his activity level has increased and he continues to go to the gym 3-4 times a week. He is currently not working. Physical examination revealed an antalgic gait, restricted range of motion of lumbar spine with spasm and tight muscle band noted on both sides of paravertebral muscles on palpation. The medications list includes Hydrocodone-acetaminophen, aspirin, desipramine, nisapan ER, simvastatin, Savella 50mg and Clonazepam. He has undergone lumbar laminectomy. He has had physical therapy, home exercise program, transcutaneous electrical nerve stimulation (TENS) unit and activity modifications for this injury. The treatment plan included refilling of Savella 50mg #60 and Hydrocodone-acetaminophen 7.5-325mg #120.

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 50 mg #60 with 1 refill: 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 Medical Treatment 2009, Section(s): Antidepressants for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 10/05/15) Milnacipran (Savella®).

Decision rationale: Savella 50 mg #60 with 1 refill. Savella is a selective serotonin and norepinephrine reuptake inhibitor (SNRI), similar to some drugs used for the treatment of depression and other psychiatric disorders. Per the cited ODG guidelines regarding savella/milnacipran, "Not recommended for chronic pain. 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) See also the Mental Chapter. 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. According to an AHRQ Comparative Effectiveness Review, the evidence is insufficient regarding milnacipran effects on VAS pain scores for adults with fibromyalgia and MDD." Evidence of fibromyalgia syndrome was not specified in the records specified. A recent detailed psychological/psychiatric evaluation note of the psychiatrist documenting the presence of significant depression, was not specified in the records provided. The patients medication list also includes a tricyclic antidepressant medication (desipramine) also used for chronic pain. The response to desipramine is not specified in the records provided. The medical necessity of Savella 50 mg #60 with 1 refill is not fully established for this patient.