MAXIMUS Federal Services

Case Number:	CM15-0208563		
Date Assigned:	10/27/2015	Date of Injury:	01/11/1999
Decision Date:	12/14/2015	UR Denial Date:	09/29/2015
Priority:	Standard	Application Received:	10/22/2015

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, Texas, Florida
Certification(s)/Specialty: Anesthesiology, Pain Management, Hospice & Palliative 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 61 year old female injured worker suffered an industrial injury on 1-11-1999. The diagnoses included bilateral lower extremity complex regional pain syndrome with spinal cord stimulator implant. On 8-6-2015 the provider reported bilateral lower extremity pain. She noted swelling and decreased range of motion of the ankles with the pain rated as 9 to 10 out of 10. On exam she was walking with a slow gait with swelling of both feet. There was allodynia in the lower extremities with skin changes including a red, mottled appearance. The medical record did not include evidence of benefit of the requested treatment. Savella had been in use at least since 5-2014. Request for Authorization date was 9-24-2015. Utilization Review on 9-29-2015 determined non-certification for Savella 50mg quantity 60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 50mg quantity 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Milnacipran (Ixel).

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

Decision rationale: Regarding the request for Savella 50mg quantity 60, Chronic Pain Treatment Guidelines state that antidepressants are first line options for chronic pain. ODG states that 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). The guidelines go on to states that, 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. Additionally, there is no identification that the Savella specifically provides any specific analgesic effect (in terms of reduced numeric rating scale or percent reduction in pain), or provides any objective functional improvement, or reduction in opiate medication use. Within the documentation available for review, there is no indication that the patient has the diagnosis of fibromyalgia. As such, the currently requested Savella 50mg quantity 60 is not medically necessary.