MAXIMUS Federal Services

Case Number:	CM15-0002653		
Date Assigned:	01/30/2015	Date of Injury:	03/09/2009
Decision Date:	03/31/2015	UR Denial Date:	12/12/2014
Priority:	Standard	Application Received:	01/06/2015

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, District of Columbia, Maryland
Certification(s)/Specialty: Anesthesiology, Pain Management

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 56 year old female, who sustained an industrial injury on 03/09/2009. She has reported subsequent neck, back and generalized pain and was diagnosed with cervical spine sprain/strain with bilateral upper extremity radiculopathy and thoracic and lumbar spine sprain/strain with right lower extremity radiculopathy, myalgia and myositis, contusion of the shoulder/arm, lumbar disc displacement and Tietze's disease. The injured worker was also diagnosed with fibromyalgia. Treatment to date for fibromyalgia has included oral medication. In a PR2 dated 11/19/2014, the injured worker was noted to have continued total body pain, chronic fatigue and problems sleeping. Objective physical examination findings showed no new joint swelling, normal neurologic examination and no rheumatoid arthritis deformities. The physician submitted a request for authorization of Savella for relief of Fibromyalgia symptoms. On 12/12/2014, Utilization Review non-certified a request for Savella 50 mg #60 with 3 refills, noting that the medication is not FDA approved at the current time. FDA guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 50 mg, sixty count: Overturned

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 ODG, Pain, Milnacipran (Savella)

Decision rationale: The MTUS is silent on the use of Savella. Per the ODG guidelines with regard to Savella: Not recommended for chronic pain. An FDA Phase III study demonstrated "significant therapeutic effects" of milnacipran for treatment of fibromyalgia syndrome. FDA has now approved milnacipran (Savella) for the management of fibromyalgia. 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.I respectfully disagree with the UR physician's denial based upon the assertion that the requested medication is not FDA approved. Per citation above it is FDA approved and supported for the treated of fibromyalgia. The request is medically necessary.