

Case Number:	CM14-0076216		
Date Assigned:	07/16/2014	Date of Injury:	01/12/2010
Decision Date:	09/11/2014	UR Denial Date:	05/01/2014
Priority:	Standard	Application Received:	05/26/2014

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 Interventional Spine 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:

The patient is a 55 years old female with an injury date on 01/12/2010. Based on the 02/07/2014 progress report provided by [REDACTED], the diagnoses are: 1. Cervical stenosis, shoulder impingement. According to this report, the patient complains of neck pain and shoulder pain. The 12/06/2013 report indicates positive impingement sign and tenderness over the neck region. MRI shows cervical stenosis at C5-C6 and C6-C7. Physical exams and MRI report were not provided in the file for review. There were no other significant findings noted on this report. The utilization review denied the request on 05/01/2014. [REDACTED] is the requesting provider and he provided treatment reports from 12/06/2013 to 02/07/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 50 mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) 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). (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.

Decision rationale: According to the 02/07/2014 report by [REDACTED], this patient presents with neck pain and shoulder pain. The provider is requesting Savella 50mg #60. For Savella, ODG Guidelines states "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, the provider did not provide the rationale why the patient needs this medication. The patient does not present with fibromyalgia as required by ODG; therefore, the request for Savella 50mg #60 is not medically necessary.

Therapentin-90, ingredients are Theramine #180, Gabapentin 300 mg #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain-Theramine.

Decision rationale: According to the 02/07/2014 report by [REDACTED], this patient presents with neck pain and shoulder pain. The provider is requesting Therapentin 90 that contains Theramin, a medical food. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG Guidelines state that "Theramine is a proprietary medication of [REDACTED] based in [REDACTED]. Its intended use is in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain." ODG further state for each ingredient, "There is no high quality peer-reviewed literature that suggests that GABA is indicated", for Choline: "There is no known medical need for choline supplementation"; L-Arginine, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, "There is no indication for the use of this product." It does not appear that there is any guideline to support this product in the management of chronic pain. Therefore, the request for Therapentin-90 is not medically necessary.