

<b>Case Number:</b>	CM13-0055006		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	09/17/2002
<b>Decision Date:</b>	03/21/2014	<b>UR Denial Date:</b>	11/07/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/20/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine, has a subspecialty in Pulmonary Diseases 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 physician 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-year-old female who reported injury on 09/17/2002. The mechanism of injury was not provided. The most recent examination revealed the patient had no new joint swelling and had a normal neurologic examination along with no rheumatoid arthritis deformities, swelling in hands, and tightness along the back. The patient was noted to be taking Trepadone, Theramine, tramadol 15%, and flurbiprofen for FMS pain. The patient indicated they had continued total body pain, chronic fatigue and problems sleeping. The request was made for medication refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**One prescription of Theramine #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 (ODG). Pain (chronic), Theramine

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

**Decision rationale:** Official Disability Guidelines indicate that Theramine is not recommended as it contains gamma-aminobutyric acid (GABA) and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There is no high quality peer reviewed literature that suggests that GABA is indicated, and for choline, there is no known medical need for choline supplementation. For L-arginine, this medication is not indicated in current references for pain or inflammation, and for L-serine, there is no indication for the use of this product. There was a lack of documentation of efficacy of the requested medication. Additionally, there was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations against the use of the medical food. Given the above, the request for 1 prescription of Theramine #60 is not medically necessary.

**One prescription of Treadone qty 90: 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).Pain (chronic), Treadone, and Official Disability Guidelines (ODG).Pain (chronic), Medical food

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

**Decision rationale:** Official Disability Guidelines indicate that Treadone is a medical food and has the blend of L-arginine, L-glutamine, choline bitartrate, L-serine, and gamma-aminobutyric (GABA). It is intended for the use in the management of joint disorders associated with pain and inflammation. There is no high quality peer reviewed literature that suggests that GABA is indicated, and for choline, there is no known medical need for choline supplementation. For L-arginine, this medication is not indicated in current references for pain or inflammation, and for L-serine, there is no indication for the use of this product. Given the above and the lack of documentation of the efficacy of the requested medication, along with the lack of documentation of exceptional factors, the request for 1 prescription of Treadone #90 is not medically necessary.

**Unknown prescription of Tramadol: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medication for Chronic Pain, ongoing management Page(s): 60,78. Decision based on Non-MTUS Citation (Web version) FDA.GOV

**Decision rationale:** California MTUS Guidelines indicate that opioids are appropriate in the treatment of chronic pain. There should be documentation of an objective decrease in the VAS score, objective functional improvement, documentation of adverse side effects, and documentation of evidence that the patient is being monitored for aberrant drug behavior. The

clinical documentation submitted for review failed to provide documentation of the above. Additionally, there was a lack of documentation of the strength and quantity, per the submitted request. The request, per the physician was for tramadol 10%, for which a thorough search of FDA.gov did not indicate there was a formulation of topical tramadol that had been FDA approved. It is approved for oral use only. Given the above and the lack of clarification, as well as the lack of documentation of the patient's objective functional improvement, decreased VAS score, and evidence of monitoring for aberrant behavior, the request for Unknown prescription of Tramadol is not medically necessary.

**One urine drug testing:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Michigan Automated Prescribing Service (MAPS) (online version), University of Michigan Health System Guidelines for Clinical Care, Managing Chronic Non-terminal Pain, pg(s) 10;32

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ongoing management Page(s): 78.

**Decision rationale:** California MTUS indicates that the use of urine drug screening is for patients with documented issue of abuse, addiction, or poor pain control. The clinical documentation submitted for review failed to provide the patient had documented issues of abuse, addiction or poor pain control. There was a lack of documented rationale for the request. Given the above, the request for 1 urine drug testing is not medically necessary.