

<b>Case Number:</b>	CM14-0219301		
<b>Date Assigned:</b>	01/09/2015	<b>Date of Injury:</b>	05/04/1995
<b>Decision Date:</b>	03/09/2015	<b>UR Denial Date:</b>	12/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/31/2014

### 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. 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: Ohio, West Virginia

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Medical Toxicology

### 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 46 year old male, who sustained an industrial injury on 5/04/1995. The mechanism of injury has not been provided with the clinical documentation submitted for review. He has reported back pain. The diagnoses have included lumbar radiculopathy and degenerative disc disease. Currently, the IW complains of lower back pain with allodynia. He has had a recent flare up with intermittent back pain. His symptoms are helped with his current medication regimen. There is residual lower back pain but improvement of numbness and left leg pain. Objective exam reveals muscle spasms of the left paraspinal muscles. There is good range of motion of the lumbar spine. Extension is 20 degree and flexion is 40 degrees. Bilateral lateral bending is 15 degrees and rotation is 20 degrees. There is pain with palpation of the left SI (sacro-iliac) joint. There is positive FABER sign on the left but much less pain. He has a limp. The treatment plan includes medication management. Treatment to date has included H wave. On 12/24/2014, Utilization Review non-certified a prescription for Theramine #90 and Tramadol ER 150mg noting the lack of objective benefit to use. The MTUS and ODG guidelines were cited. On 12/31/2014, the injured worker submitted an application for IMR for review of Theramine #90 and Tramadol ER 150mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine TID #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 Chapter, Theramine(r)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain (Chronic), Theramine and medical food

**Decision rationale:** ODG states that a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain." See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The ODG guidelines do not support the use of Theramine. As such the request for Prospective request for 1 prescription of Theramine #90 is not medically necessary.

**Tramadol ER 150mg QD #30:** 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 Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram; ½)

**Decision rationale:** MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of tramadol prior to

the initiation of this medication. As such, the request for tramadol 150mg x30 is deemed not medically necessary.