

<b>Case Number:</b>	CM14-0120961		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	06/07/2007
<b>Decision Date:</b>	09/17/2014	<b>UR Denial Date:</b>	07/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/31/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, Pain Medicine and is licensed to practice in Texas and Oklahoma. 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 injured worker is a 60-year-old male with a reported date of injury on 06/07/2007. The mechanism of injury was noted to be a twinge in the left lower back. His diagnoses were noted to include chronic low back pain, gastro esophageal reflux disease, and positive helicobacter pylori, osteoarthritis, and obstructive sleep apnea. His previous treatments were noted to include medications, physical therapy, and surgery. The progress note dated 12/02/2013 revealed complaints of lumbar spine, bilateral upper extremity, bilaterally knee pain. The injured worker reported the medications were on as needed basis for pain, but his back would still have bad pain. The physical examination of the lumbar spine noted a painful range of motion with tenderness to palpation and spasms to the lumbar paravertebral muscles. There was a positive straight leg raise noted bilaterally that caused low back pain. The Request for Authorization form was not submitted within the medical records. The request was for Omeprazole #180 (DOS missing), Theratramadol #90 (DOS missing), and Theramine #90 (DOS missing). However, the provider's rationale was not submitted within the medical records.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retro: Omeprazole #180 (DOS missing): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68.

**Decision rationale:** The request for Retro: Omeprazole #180 (DOS missing) is not medical necessary. The injured worker complained primarily of back and extremity pain. The California Chronic Pain Medical Treatment Guidelines recommend for the physician to determine if the patient is at risk for gastrointestinal events such as age greater than 65 years, history of peptic ulcer, gastrointestinal bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAIDs. There is a lack of documentation regarding abdominal complaints or utilizing NSAIDs to warrant this medication. Additionally, the request failed to provide the dosage and frequency at which this medication is to be utilized. Therefore, the Retro: Omeprazole #180 (DOS missing) is not medically necessary.

**Retro: Theratramadol #90 (DOS missing):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Work Loss Data Institute, Official Disability Guidelines Treatment in Workers Compensation, 7th Edition, 2010; Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Medical food.

**Decision rationale:** The request for Retro: Theratramadol #90 (DOS missing) is non-certified. The injured worker is using tramadol for pain. According to the California Chronic Pain Medical Treatment Guidelines, the ongoing use of opioid medications may be supported with detailed documentation of pain relief, functional status, appropriate medication use, and side effects. The guidelines also state that the 4 A's for ongoing monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors, should be addressed. There is a lack of documentation regarding evidence of decreased pain on a numerical scale with the use medications. There is lack of documentation regarding improved functional status with activities of daily living with the use of medications. There is lack of documentation regarding side effects and as to whether the injured worker has had consistent urine drug screens and when the last test was performed. The Official Disability Guidelines state a medical food is a food which is formulated to be consumed or administered enterally or under the supervision of the physician, and which is intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The guidelines state for gamma aminobutyric acid is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer reviewed literature that suggests that GABA is indicated for treatment of insomnia. Theratramadol consists of tramadol and gamma aminobutyric acid, which is not recommended by the guidelines. Therefore, due to the lack of documentation regarding evidence of significant pain relief, improved functional status, side effects, and consistent urine drug screens, as well as the fact that the gamma aminobutyric acid is not recommended by the guidelines, the Theratramadol is not appropriate at this time. Therefore, the request is not medically necessary.

**Retro: Theramine #90 (DOS missing): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Work Loss Data Institute, Official Disability Guidelines Treatment in Workers Compensation, 7th Edition online Medical Chapter on Pain.

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

**Decision rationale:** Theramine is a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine). The retrospective request for Theramine #90 (DOS missing) is non-certified. Theramine consists of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5 hydroxy tryptophan, gamma aminobutyric acid, and L-serine. The Official Disability Guidelines define medical food as a food which is formulated to be consumed or administered enterally or under the supervision of the physician, and which is intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The guidelines state L-arginine is not indicated in current references for pain or inflammation; instead, it is indicated to detoxify urine. The guidelines state L-serine does not have an indication for the use of this supplement. The guidelines state gamma aminobutyric acid is indicated for epilepsy, spasticity, and tardive dyskinesia. There is no high quality that suggests that GABA is indicated for the treatment of insomnia. The guidelines state there is no known medical need for choline supplementation except for the case of long term parenteral or for individuals with choline deficiency secondary to liver deficiency. The guidelines state 5 hydroxy tryptophan is found to be possibly effective in the treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression. There is lack of documentation regarding the efficacy of this medication. The guidelines do not recommend L-serine, as there is no indication for use of that supplement and choline bitartrate has no known medical need except for choline deficiency secondary to liver deficiency, which is not indicated with this injured worker. Gamma aminobutyric acid is indicated for epilepsy, spasticity, and tardive dyskinesia, which is not indicated with this injured worker. Therefore, Theramine is not supported by the guidelines. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.