

Case Number:	CM15-0118486		
Date Assigned:	06/26/2015	Date of Injury:	03/18/2007
Decision Date:	08/25/2015	UR Denial Date:	06/08/2015
Priority:	Standard	Application Received:	06/19/2015

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: New York

Certification(s)/Specialty: Pediatrics, Internal Medicine

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 48-year-old male, who sustained an industrial injury on March 18, 2007. He reported heavy pipes fell from a forklift onto him. The injured worker was diagnosed as having status post post-traumatic brain injury/post-concussion syndrome, status post umbilical hernia surgery, status post traumatic cataract surgery, constipation, hypertension, hyperlipidemia, obstructive sleep apnea, chest pain, shortness of breath, and sleep disorder. Treatment to date has included a transthoracic echocardiogram, cortisone injections to the left hip and left shoulder, x-rays, continuous positive airway pressure (CPAP) and medication. Currently, the injured worker complains of unchanged sleep quality, constipation, headaches, and depression/anxiety. The Secondary Treating Physician's report dated May 13, 2015, noted the injured worker reported improved hypertension and shortness of breath. Physical examination was noted to show the injured worker ambulated with a cane and an awkward gait. The abdomen was noted to be soft with normoactive bowel sounds, and 1+ epigastric/right upper quadrant/umbilical tenderness to palpation. A MRI of the brain was noted to be pending scheduling. The treatment plan was noted to include a request for a cardiology consultation, follow-up with the neurologist, continued adherence to a course of sleep hygiene and a low-cholesterol, low glycemic, low sodium diet. Medications prescribed with two refills included Lisinopril, Gemfibrozil, Lovaza, Crestor, ASA, Theramine, Trepadone, and Tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #60 (6 bottles) with 2 refills: 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) Medical food, Theramine.

Decision rationale: The MTUS is silent regarding Theramine. The Official Disability Guidelines (ODG) notes that Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). Medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. A review of the August 6, 2014 laboratory studies was noted to show the cholesterol, and triglycerides elevated, and the HDL decrease, with all other studies unremarkable. The physician did not include discussion of the diagnosis that was requiring specific dietary management with Theramine. The documentation provided did not address the injured worker's response to the use of the Theramine. Therefore, based on the Official Disability Guidelines (ODG), the documentation provided did not support the medical necessity of the request for Theramine #60 (6 bottles) with 2 refills.

Trepadone #90 (4bottles) with 2 refills: 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) Medical food, Trepadone.

Decision rationale: The MTUS is silent regarding Trepadone. The Official Disability Guidelines (ODG) notes that Trepadone is not recommended for the treatment of chronic pain. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with

pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. The 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA are all indicated as having no role for these supplements as treatment for chronic pain. Current literature suggests omega-3 fatty acids for treatment of certain cardiovascular and lipid conditions, treatment of rheumatoid arthritis, and for selected patients for depression (primarily those who are unable to take conventional antidepressants). There is insufficient evidence to support use for osteoarthritis or for neuropathic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. A review of the August 6, 2014 laboratory studies was noted to show the cholesterol, and triglycerides elevated, and the HDL decrease, with all other studies unremarkable. The physician did not include discussion of the diagnosis that was requiring specific dietary management with Trepadone. The documentation provided did not address the injured worker's response to the use of the Trepadone. Therefore, based on the Official Disability Guidelines (ODG), the documentation provided did not support the medical necessity of the request for Trepadone #90 (4bottles) with 2 refills.

Tramadol 50mg #60 (3 bottles) with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines notes that ongoing management of opioid therapy should include the lowest possible dose prescribed to improve pain and function, and ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. On-going management should include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain lasts. Satisfactory response to treatment may be indicated by the injured worker's decreased pain, increased level of function, or improved quality of life. The guidelines note to continue opioids when the injured worker has returned to work, and if the injured worker has improved functioning and pain. Tramadol (Ultram) is a centrally acting

synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. The documentation provided did not include documentation of objective, measurable improvement in pain relief with the Tramadol, the average pain, the intensity of pain after taking the medication, how long it takes for pain relief, how long the pain lasts, or objective, measurable improvement in function or quality of life withy use of the Tramadol. Therefore, based on the MTUS guidelines, the documentation provided did not support the medical necessity of the request for Tramadol 50mg #60 (3 bottles) with 2 refills.