

Case Number:	CM14-0077003		
Date Assigned:	07/18/2014	Date of Injury:	04/01/2005
Decision Date:	04/16/2015	UR Denial Date:	05/16/2014
Priority:	Standard	Application Received:	05/27/2014

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: New Jersey, Michigan, California
 Certification(s)/Specialty: Neurology, Neuromuscular 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 40 year old male, who sustained an industrial injury on 4/1/2005. The current diagnoses are degenerative disc disease of the lumbar spine, low back pain, and chronic pain syndrome. Treatment to date has included medications, ice/heat, and home exercise program. According to the progress report dated 3/27/2014, the injured worker complains of neck pain, upper, mid, and lower back pain, bilateral hip pain, and pain in buttocks. He describes the pain as sharp, pins and needles, and electric. The pain is rated 9/10 on a subjective pain scale. The current medications are Norco, Voltaren, Lunesta, Sentra PM, Theramine, and topical compound cream. The current plan of care includes Theramine 101.5-335mg TID 90/30 days x 6 months, Voltaren 1 percent gel 1-2 to skin, 500mg/30 days 6 months #5, and Norco 10/325 NTE 7/day, 210/30 x 6 months.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine 101.5-335mg TID 90/30 days x mos: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain (5/15/14) Insomnia treatment-Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation

<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Medicalfood>.

Decision rationale: According to ODG guidelines, medical food. "Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered entirely 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." 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. See Food labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 FR 60366 at 60377, November 27, 1991). Medical foods are exempted from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343 (q) (5) (A) (iv)). Medical foods do not have to be registered with the FDA. (CFSAN, 2008) Current available medical food products: Choline: Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. (AltMedDex, 2008) (Clinical Pharmacology, 2008) Glutamic Acid: This supplement is used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine. (AltMedDex, 2008) (Lexi-Comp, 2008) 5-hydroxytryptophan: This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. (De Benedittis, 1985) (Klarskov, 2003) (AltMedDex, 2008) (Lexi-Comp, 2008) Gamma-aminobutyric acid (GABA): This supplement 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. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety. Dose reductions are indicated for a creatinine clearance > 60 ml/min. (AltMedDex, 2008) In this low quality RCT, with no description for the actual sleep disorder, an amino acid preparation containing both GABA and 5-hydroxytryptophan reduced time to fall asleep, decreased sleep latency, increased the duration of sleep, and improved quality of sleep. (Shell, 2009) L-Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement. L-Arginine: This supplement is not indicated in current references for pain or

"inflammation." It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome. (AltMedDex, 2008) (CFSAN, 2008) (Clinical Pharmacology, 2008) (Lexi-Comp, 2008) (Micromedex, 2008) Honey & cinnamon: Recommended as an option for arthritis pain. See separate listing for Honey & cinnamon. Limbrel (flavocoxid): Under study as an option for arthritis in patients at risk of adverse effects from NSAIDs, with recent evidence that Limbrel is capable of causing acute liver injury and should be used with caution. (Chalasan, 2012) See separate listing for Limbrel (flavocoxid/ arachidonic acid). See also NSAIDs, GI symptoms & cardiovascular risk; & NSAIDs, hypertension and renal function. See also Compound drugs; Co-pack drugs; Physician-dispensed drugs; Repackaged drugs. For brand names of medical foods and their respective ingredients, see Deplin (L-methylfolate); GABAdone; Sentra PM; Theramine; Trepadone; & UltraClear". There is no controlled studies supporting the safety and efficacy for the use of Theramine for the treatment of pain. Furthermore, there no documentation that the patient suffered from a nutrition deficit that requires the use of Theramine. Based on the above, the prescription of Theramine 101.5-335mg TID 90/30 days x mos is not medically necessary.

Voltaren 1 percent gel 1-2 to skin, 500mg/30 days 6 months #5: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Nonselective NSAIDS Page(s): 111, 107.

Decision rationale: Voltaren Gel (Diclofenac) is a nonsteroidal anti-inflammatory drug (NSAID). According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111), topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. There is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Diclofenac is used for osteoarthritis pain of wrist, ankle and elbow and there is no strong evidence for its use for spine pain such as cervical spine pain, shoulder and knee pain. There is no evidence of right upper extremity osteoarthritis. Therefore, the request for Voltaren gel 1% is not medically necessary.

Norco 10/325 NTE 7/day, 210/30 x mos: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 76-79.

Decision rationale: According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral

analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. According to the patient file, there is no objective documentation of pain and functional improvement to justify continuous use of Norco. Norco was used for longtime without documentation of functional improvement or evidence of return to work or improvement of activity of daily living. Therefore, the prescription of Norco 10/325mg is not medically necessary.