

<b>Case Number:</b>	CM15-0035906		
<b>Date Assigned:</b>	03/04/2015	<b>Date of Injury:</b>	08/12/2013
<b>Decision Date:</b>	04/13/2015	<b>UR Denial Date:</b>	02/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/25/2015

### 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 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 34 year old male injured worker suffered an industrial injury on 8/12/2013. The diagnoses were displacement of lumbar intervertebral disc without myelopathy, lumbosacral neuritis or radiculitis, facet joint syndrome and insomnia. The treatments were medications. The treating provider reported low back pain that radiated to the right lower extremity 7/10. There was tenderness of the lumbar spine and facet joints with reduced range of motion along with positive straight leg raise. The Utilization Review Determination on 2/24/2015 non-certified: 1. Quazepam 15 mg #30, ODG2, Tramadol 150 mg #60, MTUS3, Gabadone #60, ODG

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Quazepam 15 mg #30:** 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.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** According to MTUS guidelines, benzodiazepines are not recommended for long term use for pain management because of unproven long term efficacy and because of the risk of dependence. Most guidelines limit their use to 4 weeks. Quazepam has been used for more than 4 weeks without documentation of improvement of the patient's condition. Therefore the request for 30 Quazepam 15mg is not medically necessary.

**tramadol 150 mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113.

**Decision rationale:** According to MTUS guidelines, Ultram (Tramadol) 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. Although, Tramadol may be needed to help with the patient pain, there is no clear evidence of objective and recent functional and pain improvement from its previous use. There is no clear documentation of the efficacy/safety of previous use of tramadol. There is no recent evidence of objective monitoring of compliance of the patient with his medications. Therefore, the prescription of Tramadol 150mg #60 is not medically necessary.

**Gabalone #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), 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 hypochlohydria 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 are no controlled studies supporting the safety and efficacy for the use of Gabadone for the treatment of pain. Furthermore, there no documentation that the patient suffered from a nutrition deficit that requires the use of Gabadone. Based on the above, the prescription of Gabadone #60 is not medically necessary.