

<b>Case Number:</b>	CM14-0198224		
<b>Date Assigned:</b>	12/15/2014	<b>Date of Injury:</b>	09/22/2010
<b>Decision Date:</b>	03/19/2015	<b>UR Denial Date:</b>	11/17/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2014

### 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 patient is a 48 year old woman who sustained a work-related injury on September 22 2010. Subsequently, the patient developed a chronic right elbow and wrist pain. According to a progress report dated on September 22 2014, the patient was complaining of right shoulder and elbow pain with a severity rated 8/10 and right wrist pain. The patient physical examination demonstrated cervical and right shoulder tenderness with reduced range of motion. The patient was diagnosed with cervical disc disease, cervical radiculopathy, cervical facet syndrome and status post right shoulder arthroscopy. The provider requested authorization for the following medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine #60 with 1 refill:** 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, Medical food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <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. (CFR, 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) (CFSSAN, 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. (Chalasani, 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 #60 with 1 refill is not medically necessary.

**Tramadol 50mg #60 with 1 refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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. Therefore, the prescription of Pharmacy purchase of Tramadol 50mg is not medically necessary.

**Medrox patches x 1 month:** 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 Page(s): 111.

**Decision rationale:** Medrox ointment is formed by the combination of methyl salicylate, capsaicin, and menthol. 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. That 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. Medrox patch contains capsaicin a topical analgesic not recommended by MTUS. Furthermore, there is no documentation of failure or intolerance of first line oral medications for the treatment of pain. Based on the above Medrox patches x 1 month is not medically necessary.

**Urine toxicology screen:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, steps to avoid misuse/addiction Page(s): 77-78; 94.

**Decision rationale:** According to MTUS guidelines, urine toxicology screens is indicated to avoid misuse/addiction. Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. In this case, there is no documentation of drug abuse or aberrant behavior. There is no documentation of drug abuse or misuse from previous urine drug screen. There is no rationale provided for requesting UDS test. Therefore, Urine toxicology screen is not medically necessary.

**Refill of Protonix:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI and cardiovascular risk factors.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 102.

**Decision rationale:** According to MTUS guidelines, Protonix is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. There is no documentation that the patient is at an increased risk of GI bleeding. Therefore the prescription of Refill of Protonix is not medically necessary.

**Refill of Preparation H Cream: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/bactroban-cream.html>

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Preparation\_H [http://en.wikipedia.org/wiki/Preparation\\_H\\_Hemorrhoids\\_Medication](http://en.wikipedia.org/wiki/Preparation_H_Hemorrhoids_Medication).  
<http://emedicine.medscape.com/article/775407-medication#showall>

**Decision rationale:** According to Medscape, topical cream could be used in hemorrhoid treatment. There is no clinical evidence supporting the patient is suffering from hemorrhoids. Therefore, the prescription of H cream is not medically necessary.

**Amitiza: 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,

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioid induced constipation treatment

**Decision rationale:** MTUS guidelines did not address the use of Amitiza for constipation treatment. According to ODG guidelines, Amitiza is recommended as a second line treatment for opioid induced constipation. The first line of measures are: increasing physical activity, maintaining appropriate hydration, advising the patient to follow a diet rich in fiber, using some laxatives to stimulate gastric motility, and use of some other over the counter medications. It is not clear from the patient file that the first line measurements were used. Therefore the use of Amitiza is not medically necessary.

**Probiotics: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Viral Gastroenteritis Treatment & Management. <http://emedicine.medscape.com/article/176515-treatment>

**Decision rationale:** According to Medscape, probiotic is indicated in case of GI infection. There is no documentation of GI symptoms and laboratory evidence supporting the use of probiotics. Therefore, the request for Probiotic prescription is not medically necessary.