

Case Number:	CM15-0129754		
Date Assigned:	07/16/2015	Date of Injury:	10/27/2009
Decision Date:	08/17/2015	UR Denial Date:	06/18/2015
Priority:	Standard	Application Received:	07/06/2015

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, Alabama, 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 57 year old male patient who sustained an industrial injury on 10/27/2009. The accident was described as while working regular duty as a laborer he experienced cumulative trauma over the course of employment resulting in injury. A primary treating office visit dated 07/23/2014 reported the patient with subjective complaint of having headaches, neck pain, mid to upper back pain, right shoulder and arm pain, right elbow forearm, right knee and right ankle foot pains. The low back pain also radiates in the pattern of bilateral L4, L5 and S1 dermatomes along with parasthesia's into the right hand and wrist. The patient uses crutches for ambulation and there is pending extracorpeal therapy, magnetic resonance imaging and an orthopedic spine consultation. The plan of care noted the patient continuing physical therapy session, prescribed two compound topical creams, transcutaneous patches and batteries and obtaining a urine screening. The patient has been declared permanent and stationary. Two months later on 09/03/2014 at a follow up visit the plan of care noted physical therapy session being put on hold. An interferential unit was prescribed. A recent MRI done on 08/02//2014 reported right knee meniscal tear, and bucket handle tear, tendinitis, and chondromalacia. At an initial spine consultation dated 09/10/2014 the following diagnoses were applied: spondylolisthesis grade II L5-S1 with bilateral severe foraminal narrowing; L4-5 rupture central and right sided, and a right sided radiculopathy with weakness. There is recommendation to undergo surgical intervention at L5-S1, L4-5.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 5/325mg #60: Upheld

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

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's 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 5/325mg #60 is not medically necessary.

1 Power uplift seat: 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) Durable medical equipment (DME) Durable medical equipment (DME).

Decision rationale: According to ODG guidelines, DME Recommended generally if there is a medical need and if the device or system meets Medicare's definition of durable medical equipment (DME) below. Most bathroom and toilet supplies do not customarily serve a medical purpose and are primarily used for convenience in the home. Medical conditions that result in physical limitations for patients may require patient education and modifications to the home environment for prevention of injury, but environmental modifications are considered not primarily medical in nature. Certain DME toilet items (commodes, bed pans, etc.) are medically necessary if the patient is bed- or room-confined, and devices such as raised toilet seats, commode chairs, sitz baths and portable whirlpools may be medically necessary when prescribed as part of a medical treatment plan for injury, infection, or conditions that result in physical limitations. Many assistive devices, such as electric garage door openers,

microwave ovens, and golf carts, were designed for the fully mobile, independent adult, and Medicare does not cover most of these items. See also specific recommendations here: Aquatic therapy; Bathtub seats; BioniCare knee device; Bone growth stimulators; Braces; Canes; Cold/heat packs; Compression cryotherapy; Continuous-flow cryotherapy; Continuous passive motion (CPM); Crutches; Cryocuff; Cryotherapy; Dynamic splinting systems; Dynasplint; Electrical stimulators (E-stim); Electromyographic biofeedback treatment; ERMI knee Flexionater/ Extensionater; Flexionators (extensionators); Exercise equipment; Game Ready; accelerated recovery system; Home exercise kits; Joint active systems (JAS) splints; Knee brace; Lymphedema pumps; Mechanical stretching devices (for contracture and joint stiffness); Motorized scooters; Neuromuscular electrical stimulation (NMES devices); Orthoses; Post-op ambulatory infusion pumps (local anesthetic); Power mobility devices (PMDs); RS-4i sequential stimulator; Scooters; Shower grab bars; TENS (transcutaneous electrical nerve stimulation); Therapeutic knee splint; Treadmill exerciser; Unloader braces for the knee; Vacuum-assisted closure wound-healing; Vasopneumatic devices (wound healing); Walkers; Walking aids (canes, crutches, braces, orthoses, and walkers); Wheelchair; Whirlpool bath equipment. The term DME is defined as equipment which: (1) Can withstand repeated use, i.e., could normally be rented, and used by successive patients; (2) Is primarily and customarily used to serve a medical purpose; (3) Generally is not useful to a person in the absence of illness or injury; and (4) Is appropriate for use in a patient's home. (CMS, 2005) There is no justification for the use of uplift seat in this case. The patient weakness is not enough severe to require a power uplift seat. There is no documentation of motor deficit that requires a DME for mobility. Therefore, the request for 1 Power uplift seat is not medically necessary.

Trepadone #120: 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
<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. (Alt MedDex, 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; and UltraClear'. There are no controlled studies supporting the safety and efficacy for the use of Trepadone for the treatment of pain. Furthermore, there no documentation that the patient suffered from a nutrition deficit that requires the use of Trepadone. Based on the above, the prescription of Trepadone #120 is not medically necessary.