

Case Number:	CM15-0013327		
Date Assigned:	02/20/2015	Date of Injury:	08/01/2012
Decision Date:	04/09/2015	UR Denial Date:	01/09/2015
Priority:	Standard	Application Received:	01/23/2015

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 8/1/13. He has reported back pain with radiation down bilateral legs. The diagnoses have included chronic intractable lower back pain, degenerative disc disease, lumbar spine, disc herniation lumbar spine, radiculitis bilateral lower extremities, neuropathic pain, greater trochanteric bursitis bilateral hips, depression and cervical radiculitis left upper extremity. Treatment to date has included pain management, medications and activity restrictions. (MRI) magnetic resonance imaging of lumbar spine performed on 5/22/14 revealed mild disc desiccation of L4-5 and L5-S1 with no stenosis or neural foraminal narrowing. Currently, the injured worker complains of ongoing lower back pain with radicular symptoms down left lower extremity and neck pain with radiculitis down the upper extremities. Physical exam dated 12/19/14 noted normal exam of cervical spine, lumbar spine/thoracic spine with tenderness in the paralumbar musculature area and spasming in the paralumbar musculature and he noted relief with medications. On 1/9/15 Utilization Review non-certified (MRI) magnetic resonance imaging of brain, Pulmonary Function Testing, electrocardiogram, impedance cardiography, cardio respiratory testing, noting insufficient information to establish medical necessity; Hypertensa 1 bottle #90, Sentra AM 1 bottle #60, Sentra PM # 60 and Probiotics twice a day# 60, noting they are not recommended for chronic pain. The MTUS, ACOEM, ODG and Non-MTUS Guidelines were cited. On 1/24/15, the injured worker submitted an application for IMR for review of (MRI) magnetic resonance imaging of brain, Pulmonary function testing, electrocardiogram, impedance cardiography,

cardio respiratory testing, Hypertensa 1 bottle #90, Sentra AM 1 bottle #60, Sentra PM # 60 and Probiotics twice a day# 60.

IMR ISSUES, DECISIONS AND RATIONALES

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

MRI of the brain: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Brain, MRI.

Decision rationale: ODG states Neuroimaging is not recommended in patients who sustained a concussion/mild TBI beyond the emergency phase (72 hours post-injury) except if the condition deteriorates or red flags are noted. (Cifu, 2009) See also Diffusion tensor imaging (DTI). ODG provides additional indications for magnetic resonance imaging: To determine neurological deficits not explained by CT. To evaluate prolonged interval of disturbed consciousness. To define evidence of acute changes super-imposed on previous trauma or disease. The treating physician does not document any injury, re-injury, focal neurologic deficits, red-flags, or a significant change in symptoms from the previous imaging. As such, the request for MRI of the brain is not medically necessary.

Hypertensa 1 bottle #90: 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, 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) Pain, Medical food.

Decision rationale: Hypertensa is L-Arginine. The MTUS is silent on the use of L-Arginine. The ODG states that L-Arginine is considered a medical food and as such, not recommended for chronic 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. FDA defines a medical food as a food which is formulated to be consumed or administered internally 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. ODG further goes on to state that, 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)As such, the request for Hypertensa 1 bottle #90 is not medically necessary.

Sentra AM 1 bottle #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), Pain, 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) Pain, Medical food.

Decision rationale: Sentra AM is a medical food with choline bitartrate, L-glutamate and other neurotransmitter. The MTUS is silent on choline and L-glutamate. The ODG states that such compounds are medical foods and as such, not recommended for chronic 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. FDA defines a medical food as a food which is formulated to be consumed or administered internally 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.ODG further goes on to state, 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)As such, the request for Sentra AM 1 bottle #90 is not medically necessary.

Sentra PM #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), Pain, 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) Pain, Medical food.

Decision rationale: Sentra PM is a medical food with choline bitartrate, hydroxytryptophan, L-glutamate and other neurotransmitter. The MTUS is silent on choline and L-glutamate. The ODG states that such compounds are medical foods and as such, not recommended for chronic 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. FDA defines a medical food as a food which is formulated to be consumed or administered internally 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. ODG further goes on to state, 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) As such, the request for Sentra PM 1 bottle #60 is not medically necessary.

Probiotics #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), Pain, Medical food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate probiotics Rousseaux C et al, Lactobacillus acidophilus modulates intestinal pain and induces opioid and cannabinoid receptors. Nat Med. 2007;13(1):35.

Decision rationale: The MTUS and ODG are silent on Probiotics. Other resources were used. Probiotics are microorganisms shown to have beneficial properties in the host. Probiotics have been demonstrated to suppress the growth or epithelial binding/invasion by pathogenic bacteria, improved intestinal barrier function, modulate the immune system and pain perception. One study found that oral administration of specific Lactobacillus strains induced the expression of mu-opioid and cannabinoid receptors in intestinal epithelial cells, and mediated

analgesic functions in the gut-similar to the effects of morphine. This affect was limited to the gut in those patients with irritable bowel. In this case, it is not clear what the indication is for the probiotics. The patient is not on antibiotics and does not have a history of irritable bowel. As such, the request for probiotics is not medically necessary.

Pulmonary function testing: 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), Pulmonary function testing.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pulmonary, Pulmonary function testing.

Decision rationale: ODG states, Recommended as indicated. Separated into simple spirometry and complete pulmonary function testing. Additionally, also useful in asthmatics is the use of peak flow meters to determine the presence of asthma, the response to treatment, and exacerbations of asthma. Recommended in asthma. (NHLBI, 2007) In other lung diseases, it can be used to determine the diagnosis and provide estimates of prognosis. In these diseases, the complete PFT is utilized and, on occasions, incorporates pulmonary exercise stress testing. Recommended for the diagnosis and management of chronic lung diseases. (NHLBI/WHO, 2007) Lastly, it is recommended in the pre-operative evaluation of individuals who may have some degree of pulmonary compromise and require pulmonary resection or in the pre-operative assessment of the pulmonary patient. Medical documents do not indicate the purpose of the request test or indications that meet guidelines. As such, there request for pulmonary function test is not medically necessary.

Electrocardiogram: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/12365074>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, Preoperative electrocardiogram (ECG).

Decision rationale: The MTUS is silent on Electrocardiograms. The ODG states that ECG is recommended for patients undergoing high-risk surgery and those undergoing intermediate-risk surgeries who have additional risk factors. Patients undergoing low-risk surgery do not require electrocardiography. Patients with signs or symptoms of active cardiovascular disease should be evaluated with appropriate testing, regardless of their preoperative status. Preoperative ECGs in patients without known risk factors for coronary disease, regardless of age, may not be necessary. Preoperative and postoperative resting 12-lead ECGs are not indicated in asymptomatic persons undergoing low-risk surgical procedures. Low risk procedures (with reported

cardiac risk generally less than 1%) include endoscopic procedures; superficial procedures; cataract surgery; breast surgery; & ambulatory surgery. An ECG within 30 days of surgery is adequate for those with stable disease in whom a preoperative ECG is indicated. (Fleisher, 2008) (Feely, 2013) (Sousa, 2013) Criteria for Preoperative electrocardiogram (ECG): High Risk Surgical Procedures: These are defined as all vascular surgical procedures (with reported cardiac risk often more than 5%, which is the combined incidence of cardiac death and nonfatal myocardial infarction), and they include: Aortic and other major vascular surgery; & Peripheral vascular surgery. Preoperative ECG is recommended for vascular surgical procedures. Intermediate Risk Surgical Procedures: These are defined as procedures with intermediate risk (with reported cardiac risk generally 1-5%), and they include: Intraperitoneal and intrathoracic surgery; Carotid endarterectomy; Head and neck surgery; & Orthopedic surgery, not including endoscopic procedures or ambulatory surgery. Preoperative ECG is recommended for patients with known CHD, peripheral arterial disease, or cerebrovascular disease. Preoperative ECG may be reasonable in patients with at least 1 clinical risk factor: History of ischemic heart disease; History of compensated or prior HF; History of cerebrovascular disease, diabetes mellitus, or renal insufficiency. Low Risk Surgical Procedures: These are defined as procedures with low risk (with reported cardiac risk generally less than 1%), and they include: Endoscopic procedures; Superficial procedures; Cataract surgery; Breast surgery; & Ambulatory surgery. ECGs are not indicated for low risk procedures. In this case, the patient is not at high risk for a coronary event. The patient is due to have a low to intermediate risk procedure. As such, the request for electrocardiogram is not medically necessary.

Impedance cardiography: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/19619697>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Cotter G et al, Accurate, noninvasive continuous monitoring of cardiac output by whole-body electrical bioimpedance. *Chest*. 2004;125(4):1431.

Decision rationale: Both the MTUS and ODG are silent on Impedance cardiography. Impedance cardiography or electrical bioimpedance is testing that may be used in patient undergoing cardiac catheterization, cardiac bypass or in patients with decompensated heart failure. It is a surrogate measuring tool to determine cardiac output. In this case, the patient is not undergoing catheterization, bypass surgery or has a history of heart failure. There is no indication given by the requesting provider for this test. As such, the request for Impedance cardiography is not medically necessary.

Cardio respiratory testing: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/16168867>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Gibbons RJ et al, ACC/AHA 2002 guideline update for exercise testing: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1997 Exercise Testing Guidelines). Circulation. 2002;106(14):1883. Jurca RI et al, Assessing cardiorespiratory fitness without performing exercise testing> Am J prev Med 2005 OCT:29(3): 185-193.

Decision rationale: The MTUS and ODG are silent on Cardio respiratory testing, other guidelines where used. The ACC and AHA state that the 3 main indications for cardio respiratory testing or functional exercise testing include, Evaluation of exercise capacity and response to therapy in patients with heart failure (HF) who are being considered for heart transplantation Assistance in the differentiation of cardiac versus pulmonary limitations as a cause of exercise-induced dyspnea or impaired exercise capacity when the cause is uncertain. Evaluations of exercise capacity when indicated for medical reasons in patients in whom the estimates of exercise capacity from exercise test time or work rate are unreliable. This testing involves exercise. The requested and performed test here is similar to that described by Jurca et al without exercise. This testing is suggestive of the patient's cardiorespiratory fitness, however, this is not a randomized control study and the participants had maxed or near maxed NASA fitness level. In this case, there is no documentation of any of the above indications. The patient did have the above non-exercise testing with an abnormal result suggesting possible autonomic dysfunction. It is unclear how to interpret these results as the patient's baseline condition is poor. The performing physician advises further cardiorespiratory testing. It is unclear from the records what the indication for this testing is. As such, the request for Cardio respiratory testing is not medically necessary.