

Case Number:	CM15-0005837		
Date Assigned:	01/26/2015	Date of Injury:	09/01/2006
Decision Date:	03/20/2015	UR Denial Date:	12/13/2014
Priority:	Standard	Application Received:	01/12/2015

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: Hawaii, California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 51 year old female, who sustained an industrial injury on 09/01/2006. She has reported worsened gastroesophageal symptoms on 11/2014. The diagnoses have included carpal tunnel syndrome, right shoulder impingement status post surgery, left shoulder impingement syndrome, degeneration of cervical intervertebral disc, cephalgia, abdominal pain, and gastroesophageal reflux disease. Treatment to date has included medications and surgical intervention. Medications have included Nexium, Gaviscon, Carafate, Atenolol, Metformin, and Fioricet. Surgical intervention has included right shoulder subacromial decompression, performed on 06/01/2010. A progress noted from the treating physician, dated 11/20/2014, documented a follow-up visit with the injured worker. The injured worker reported uncontrolled blood glucose and worsened gastroesophageal reflux symptoms; migraine headaches; forgetfulness; dysphagia; shortness of breath, and sleep is problematic. Objective findings included 3+ tenderness to palpation over the entire abdomen with positive guarding. The treatment plan has included continuation and prescriptions for medications; continue diet restrictions; neurology consultation; and follow-up evaluation in three months. On 12/13/2014 Utilization Review noncertified 1 prescription of Nexium 40 mg QTY: 30, with 2 refills. The MTUS, Chronic Pain Medical Treatment Guidelines was cited. On 01/02/2015, the injured worker submitted an application for IMR for review of a prescription of Nexium 40 mg QTY: 30, with 2 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nexium 40 MG Qty 30 with 2 Refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

Decision rationale: MTUS states "Determine if the patient is at risk for gastrointestinal events: (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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease : (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)." "The patient does complain of subjective reflux. The treating physician does not document evaluation was performed to confirm the diagnosis of GI reflux. Additionally, a trial of omeprazole or lansoprazole was not noted in the medical records prior to requesting Nexium. As such, the request for Nexium 40 MG Qty 30 with 2 Refills is not medically necessary at this time.

Sentra AM #60/ 3 bottles: 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), Treatment Index, 12th Edition (web), 2014, Medical Foods

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 that contains choline and acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. The ODG states that a medical food is "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 eternally 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." ODG specifically states "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." Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra AM #60/ 3 bottles is not medically necessary.

Theramine #60/3 bottles: 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), Treatment Index, 12th Edition (web), 2014, Medical foods

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Theramine and medical food

Decision rationale: ODG states that a medical food is "a food which is formulated to be consumed or administered enterally 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". ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to Naproxen; Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." The ODG guidelines do not support the use of Theramine. As such the request for Theramine #60/3 bottles is not medically necessary.

Simvastatin 6mg #30 with 2 refills: 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) and Harrison's Principles of Internal Medicine, 14th Edition, Disorders of the Cardiovascular System: Hyperlipidemia, pages 996-998

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes, Statins and www.uptodate.com, Simvastatin

Decision rationale: MTUS is silent specifically with regards to Simvastatin. ODG states, "Not recommended as a first-line treatment for diabetics. Patients with DM should be screened for dyslipidemia, and therapeutic recommendations should include lifestyle changes and, as needed, consultation with a registered dietitian. Statins may be a treatment in the absence of contraindications, but recent studies have associated increased risk of DM with use of all types of statins." Uptodate states for Primary prevention:-LDL-C 190 mg/dL: High intensity therapy necessary; use alternate statin therapy (eg, atorvastatin or rosuvastatin)-Type 1 or 2 diabetes and age 40-75 years: Moderate intensity therapy: 20-40 mg once daily-Type 1 or 2 diabetes, age 40-75 years, and an estimated 10-year ASCVD risk 7.5%: High intensity therapy necessary; use alternate statin therapy (eg, atorvastatin or rosuvastatin)-Age 40-75 years and an estimated 10-year ASCVD risk 7.5%: Moderate to high intensity therapy: 20-40 mg once daily or consider using high intensity statin therapy (eg, atorvastatin or rosuvastatin)The medical records provided do not indicate cholesterol levels. Additionally, the medical records do not document the diagnosis of diabetes. As such, the request for Simvastatin 6mg #30 with 2 refills is not medically necessary at this time.

Fioricet #90 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents (BCAs) Page(s): 23.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents (BCAs) Page(s): 23.

Decision rationale: MTUS states "Not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) There is a risk of medication overuse as well as rebound headache". The treating physician has not detailed a trial and failure of first line agents and detailed why such an addictive drug is needed at this time. As such, the request for Fioricet #120 is not medically necessary.

Probiotics #60 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Harrison's Principles of Internal Medicine, 18th Edition, Disorders of the Gastrointestinal System

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental, Psychobiotics and www.uptodate.com, Probiotics for gastrointestinal diseases

Decision rationale: MTUS is silent specifically with regards to probiotics. ODG states, "Under study. Psychobiotics are live organisms (probiotics) that when ingested may produce health benefits in patients suffering from mental illness. The term psychobiotic was created as recent studies have begun to explore a possible link between probiotics and behavior. Several preclinical studies showed a link between specific probiotics and beneficial behavioral effects. Preclinical studies suggest that depression is associated with an alteration in the microbiota. Psychobiotics are good bacteria that have the potential to increase microbial diversity and treat the symptoms of depression. Human studies are still largely lacking, but one study showed that healthy volunteers who received *Lactobacillus helveticus* R0052 plus *B longum* for 30 days reported significantly lower stress levels than those who received placebo, as well as significantly reduced urinary free cortisol levels." Uptodate states "Several probiotic preparations have promise in preventing or treating various conditions. However, most studies have been small, and many have important methodologic limitations, making it difficult to make unequivocal conclusions regarding efficacy, especially when compared with proven therapies. Furthermore, considerable differences exist in composition, doses, and biologic activity between various commercial preparations, so that results with one preparation cannot be applied to all probiotic preparations." Medical documents do not detail what mental illness the requested probiotics meant for. Additionally, medical documents do not what gastrointestinal disease the requested probiotics is meant for. Medical records do not detail why exception to the guidelines are necessary. As such, the request for Probiotics #60 with 2 refills is not medically necessary at this time.

Gaviscon one bottle with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Harrison's Principles of Internal Medicine, 18th Edition, Disorders of the Gastrointestinal System: Gastroesophageal Reflux and Esophagitis, pages 1226-1227

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.uptodate.com, Clinical manifestations, diagnosis, and treatment of non-acid reflux

Decision rationale: MTUS is silent with regards to Gaviscon. Gaviscon is an antacid used for the treatment of dyspepsia and gastric acidity. Uptodate states "A report of 10 patients found that a preparation of sodium alginate and potassium bicarbonate (Gaviscon Advance) given postprandially decreased the number of acid reflux episodes and distal esophageal acid exposure 5 cm above the LES (lower esophageal sphincter)". The medical records do not document acid reflux or dyspepsia. The cited guideline source only offers one study, which has a small sample size. The treating physician does not detail extenuating circumstances to warrant usage of the

medication at this time. As such, the request for Gaviscon one bottle with 2 refills is not medically necessary.

Carafate 1g #180 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Harrison's Principles of Internal Medicine, 18th Edition, Disorders of the Gastrointestinal System: Gastroesophageal Reflux and Esophagitis, pages 1226-1227

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.uptodate.com, Pharmacology of antiulcer medications

Decision rationale: MTUS is silent specifically with regards to Carafate. Uptodate states, "Sucralfate (Carafate) is a sulfated polysaccharide, sucrose octasulfate, complexed with aluminum hydroxide. It prevents acute chemically-induced mucosal damage and heals chronic ulcers without altering gastric acid or pepsin secretion or significantly buffering acid [33, 38]. Similar to aluminum-containing antacids, sucralfate stimulates angiogenesis and the formation of granulation tissue, possibly due to growth factor binding [33]. Sucralfate also binds to the injured tissue, thereby delivering growth factors and reducing access to pepsin and acid." Medical records do not substantiate acute chemically-induced mucosal damage or chronic ulcers. Given the lack of substantiating information, the request cannot be approved at this time. As such, the request for Carafate 1g #180 with 2 refills is not medically necessary at this time.

Trepadone #90/ 3 bottles: 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), Treatment Index, 12th Edition (web), 2014, Medical Foods

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Trepadone and Medical Food

Decision rationale: MTUS is silent concerning Trepadone. ODG states that a medical food is "a food which is formulated to be consumed or administered enterally 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". ODG comments on Trepadone directly, "Trepadone is a medical food from [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)." ODG states, "Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia." Medical records do not indicate that this

medication would be used to treat epilepsy, spasticity and tardive dyskinesia. ODG states, "L-Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." This component is not indicated. ODG states, "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." Medical records do not indicate that this medication would be utilized for urine detoxification or for treatment off the other indicated reasons. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there are several components of this medication that are not recommended per guidelines. As such, the request for Trepadone #90/3 bottles is not medically necessary.

Metformin 1000mg #60 with 2 refills: 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), Treatment Index, 12th Edition (web), 2014, Diabetes

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

Decision rationale: MTUS is silent with regards to metformin. ODG states, "Recommended as first-line treatment of type 2 diabetes to decrease insulin resistance. (Nicholson, 2011) As a result of its safety and efficacy, metformin should also be the cornerstone of dual therapy for most patients. Metformin is effective in decreasing both fasting and postprandial glucose concentrations." The medical records do not substantiate the diagnosis of diabetes type 2. There are not glucose or HA1C levels to reference in the medical records. Given the lack of documentation, the requested medication cannot be approved at this time. As such, the request for Metformin 1000mg #60 with 2 refills is not medically necessary at this time.