

Case Number:	CM15-0033800		
Date Assigned:	02/27/2015	Date of Injury:	09/30/2014
Decision Date:	04/10/2015	UR Denial Date:	01/30/2015
Priority:	Standard	Application Received:	02/23/2015

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:

This 60 year old male sustained an industrial injury on 9/30/14. He subsequently reports ongoing low back pain. Diagnoses include lumbar sprain/ strain and spasm of muscle. Treatments to date have included work restrictions, use of a cane, physical therapy and prescription pain medications. An ultrasound of the groin was completed on 11/19/14 revealing a herniation. A lumbar MRI dated 12/23/14 revealed abnormalities of the spine. On 1/30/15, Utilization Review non-certified a request for Probiotics 2 times a day #60, Sentra PM, 1 bottle #60, Sentra AM, 1 bottle #60 and Prilosec 20mg daily #30. The Probiotics 2 times a day #60 request was denied based on a World Journal of Gastroenterology citation. The Sentra PM, 1 bottle #60 and Sentra AM, 1 bottle #60 were denied based on ODG guidelines. The Prilosec 20mg daily #30 was denied based on MTUS Chronic Pain guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Probiotics 2 times a day #60: 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/25546501>, World J Gastroenterol. 2014 Dec 21; 20(47).

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. 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 2 times a day #60 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, Pain.

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 foods.

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 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. 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) As such, the request for Sentra AM 1 bottle #60 is not medically necessary.

Sentra PM, 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, Pain.

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 foods.

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 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. 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.

Prilosec 20mg daily #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) 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)." The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because of the present medication regimen. As such, the request for Prilosec 20mg daily #30 is not medically necessary.