MAXIMUS Federal Services

Case Number:	CM14-0121665		
Date Assigned:	08/06/2014	Date of Injury:	11/25/2011
Decision Date:	09/11/2014	UR Denial Date:	07/03/2014
Priority:	Standard	Application Received:	08/01/2014

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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

Patient is a 47-year-old female with 11/25/11 date of injury, when patient developed throbbing pain in left foot, lower back with numbness and tingling in both legs and pain in her neck, left shoulder and arm. The doctor's progress reports are handwritten and poorly legible. The patient complaints of back pain and left lower extremity pain. Exam reveals tenderness of left foot and weakness in dorsiflexion. Diagnoses on 05/19/14 include plantar fascial fibromatosis, chronic pain syndrome, lumbago. 04/14/14 report diagnosed CRPS instead of chronic pain syndrome. 01/17/14 note states tenderness at L4-5 and L5-S1, sciatic notch tenderness, weakness of left great toe extensor and left anterior tibialis. Diagnosis included plantar fasciitis, tarsal tunnel syndrome, probable CRPS, medication induced gastritis. Progress report dated 03/19/14 states diagnosis of major depressive disorder, generalized anxiety disorder, female hypoactive sexual desire disorder due to chronic pain, insomnia, headaches, status post orthopedic surgery, gastric disturbances.

IMR ISSUES, DECISIONS AND RATIONALES

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

RESTONE 3/100MG #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines; Medical FoodsODG states that medical foods are 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 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." 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 product 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 product 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.

Decision rationale: Restone contains melatonin and tryptophan. Melatonin is listed in ODG as a treatment of insomnia, indicated for problems with sleep onset. However, the medical documentation provided does not specify sleep onset problems, noting nightmares and sleep difficulties. This does not establish the medical necessity for melatonin. L-tryptophan is an essential amino acid present in human diet. L-tryptophan is converted into 5-hydroxytryptophan (5-HTP) in the GI tract. 5-HTP then converts into serotonin and the latter can address the symptoms of anxiety. Therefore, the medical necessity for medical food RESTONE, consisting of melatonin and L-tryptophan is not established for this patient and cannot be supported by the guidelines. Recommendation is not medically necessary.

DICLOFENAC 100MG #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 47. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter: Diclofenac:Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. For a patient who has a 5% to 10% risk of having a heart attack, that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. (McGettigan, 2011) Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID. (Varas-Lorenzo, 2011) In this nationwide cohort study the traditional NSAID diclofenac was associated with the highest increased risk of death or recurrent myocardial infarction (hazard ratio, 3.26; 95% confidence interval, 2.57 to 3.86 for death/MI at day 1 to 7 of treatment) in patients with prior MI, an even higher cardiovascular risk than the selective COX-2 inhibitor rofecoxib, which was withdrawn from the market due to its unfavorable cardiovascular risk profile. (Schjerning, 2011) According to FDA MedWatch, postmarketing surveillance of topical diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. If using diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. (FDA, 2011) In 2009 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. (FDA, 2009) With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or nonpharmacological therapy should be considered. The AGS updated Beers criteria for inappropriate medication use includes diclofenac. (AGS, 2012) Diclofenac is associated with a significantly increased risk of cardiovascular complications and should be removed from essential-medicines lists, according to a new review.

Decision rationale: Patient was prescribed Diclofenac in January 2014 (per report dated 01/17/14). Guidelines do not support the prescription of Diclofenac without failure of a first-line NSAID, such as Naproxen. Diclofenac is not recommended as a first-line option, due to the multitude of its side effects. The records do not indicate an attempt of NSAID therapy with a first-line medication. In addition, NSAIDs are to be used for a shortest period of time, whereas patient is being prescribed Diclofenac since at least 01/2014. Therefore the request is not medically necessary.

CONDOLITE 500/200/150MG #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter - GlucosamineNot recommended for low back pain. Glucosamine is not significantly different from placebo for reducing pain-related disability or improving health-related quality of life in patients with chronic low back pain (LBP) and degenerative lumbar osteoarthritis, and it should not be recommended for patients with lower back pain. Glucosamine is a precursor molecule involved in building tendons, ligaments, and cartilage. It is hypothesized to restore cartilage and to have anti-inflammatory properties, and, despite conflicting data on its efficacy, has become widely used as a treatment for osteoarthritis. It has also become more widely used for LBP, including degenerative lumbar osteoarthritis. The agent used in the study - glucosamine sulfate - is relatively bioavailable. There are several possible reasons why glucosamine was not effective in this study. A likely explanation is that glucosamine may work on some joints, for example, the knee, but not the lower back. The target molecule may differ in the different joints. There seems to be more of the (proinflammatory) target molecule for glucosamine in the knee joint. The molecule is not found much in the hip, and the concentration of this substance in the low back is unkown. Another factor to consider is that LBP is caused by many different conditions, and it is possible that glucosamine could work on some, but not all, of these conditions. (Wilkens, 2010) For information on other conditions, see the PAIN Chapter of ODG Treatment.ODG Pain ChapterRecommended as an option (glucosamine sulfate only) given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). Other Medical Treatment Guideline or Medical Evidence: Condrolite is a Medical Nutritional Supplement consisting of a combination of Glucosamine sulfate 500mg, Chondroitin sulfate 200mg, and MSM 150mg. http://enovachem.us.com/portfolio/condrolite/.

Decision rationale: Medical records provided do not establish the arthritic component of the patient's pain syndrome. Glucosamine is recommended only for Osteoarthritis, particularly in the knee joint. It is not recommended for low back pain. Guideline criteria are not met and medical necessity for this prescription is not established. Therefore, request is not medically necessary.

PRILOSEC 20MG #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter: ODG states that proton pump inhibitors are recommended for patients at risk for gastrointestinal

events. (Pain Chapter).Other Medical Treatment Guideline or Medical Evidence: The FDA states that it is indicated for the treatment of GI disorders such as gastric/duodenal ulcers, GERD, erosive esophagitis, etc. It is also commonly utilized to prevent/treat the gastric irritation common in patients utilizing chronic NSAID therapy.

Decision rationale: CA MTUS and the FDA support proton pump inhibitors in the treatment of patients with GI disorders, or patients utilizing chronic NSAID therapy. Records indicate that the patient has medication-induced gastritis. However, since none of the prescriptions, are recommended for certification, specifically Diclofenac, Prilosec is also not medically necessary.