

Case Number:	CM13-0030708		
Date Assigned:	11/27/2013	Date of Injury:	06/25/2007
Decision Date:	01/24/2014	UR Denial Date:	09/17/2013
Priority:	Standard	Application Received:	09/30/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain management, has a subspecialty in Disability Evaluation, 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 physician 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.

CLINICAL CASE SUMMARY

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

Per medical records reviewed, the patient is a 56 year old female, who injured her neck, low back, and bilateral shoulders on 06/25/07 in a motor vehicle accident. The patient was working for [REDACTED] for 18 years when the injury occurred on 6/25/2007. Prior to injury the patient was working 8-10 hours a day 40-60 hour a week, with lifting a maximum of 70 pounds. On the day of the injury the patient was performing her usual and customary job when she was rear ended at a stop light. She has been complaining of sciatica for 4 years since the injury occurred. She had not been treated with an epidural. She stopped her EMG testing early due to pain from the EMG. The patient has received medication, physical therapy, anti-depressants, anti-inflammatory medications and injections. Currently the patient is experiencing aching, cramping and stabbing pain. The pain is increased by sitting, standing, laying down, bending, walking and coughing for long periods of time. The pain is rated as a 8/10 and is there constantly. The pain interferes with sleep and work. The pain causes anxiety and depression. The pain results in bladder and bowl weakness.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec, 20mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI (gastrointestinal) Symptoms and Cardiovascular Risk Page(s): 62.

Decision rationale: The Physician Reviewer's decision rationale: Prilosec, or PPI, is recommended with precautions in patients taking NSAID (non-steroidal anti-inflammatory drugs), because of potential development of gastro-intestinal bleeding. According to Chronic Pain Medical Treatment Guidelines, clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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). The patient does not fall into any of these categories. The request for Prilosec, 20mg, is not medically necessary or appropriate.

Sentra: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation USFDA Information on Medical Food, and the Journal of Central Nervous Systems Disease, 2012, no. 4, pages 65 - 72

Decision rationale: The Physician Reviewer's decision rationale: Sentra PM contains precursors to serotonin and acetylcholine in a patented system that promotes amino acid uptake and neurotransmitter release. The concentrations of amino acids are provided in low milligram doses. Sentra PM promotes specific neurotransmitter production. The amino acid precursors in the formulation augment neurotransmitters proven to be deficient in patients with sleep disorders. Serotonin and acetylcholine initiate sleep, elicit REM sleep and promote delta sleep. Serotonergic activity increases during wakefulness and is necessary to induce sleep and serotonin deficiencies that lead to insomnia. Serotonin is also involved in wakefulness. Acetylcholine activity is crucial in promoting REM sleep and agonist or supplementation leads to increased REM sleep. According to USFDA website, The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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. Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval. There was no documentation of such a specific medical disorder, disease, or condition for a distinctive nutritional requirement. The treating physician [REDACTED] in his supplemental report dated November 25, 2013 indicated that Sentra PM was prescribed "as a sleep aid that helps prolong the sleep with Ambien", however, there is no documentation that the patient sleep disorder is due to deficiency in serotonin and/or acetylcholine, for which Sentra PM is a precursor of. The request for Sentra is not medically necessary or appropriate.

Theramine foods: 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 USFDA information on Medical food

Decision rationale: The Physician Reviewer's decision rationale: According to USFDA website, The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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. Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval. According to a recent study published in MPR and online drug information resource, Theramine, a prescription-only amino acid food product, may offer a safe alternative to traditional pharmaceutical products used to treat chronic back pain, according to a presentation at PAINWeek 2012. Theramine is prescribed for patients with chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain who cannot use conventional diets or supplements. It had been shown in a previous double-blind clinical trial to be effective in the treatment of chronic low back pain when compared with naproxen, a nonsteroidal anti-inflammatory drug (NSAID). [REDACTED] from Targeted Medical Pharma, Inc., in Los Angeles, and colleagues reported the results of the randomized, double-blind, placebo-controlled that examined if medical foods can offer an alternative therapeutic approach for back pain, with fewer side effects. In 127 patients, the efficacy of Theramine for chronic back pain was compared with low-dose ibuprofen, an NSAID. Patients were randomized to one of three treatment arms: low-dose ibuprofen (n=42), Theramine (n=42), or a combination of Theramine and ibuprofen (n=43) for 28 days. Eligible patients had back pain >6 weeks. Acetaminophen was given as rescue therapy for pain, at a dosage of 650 mg-1,000 mg every 4-6 hours, for a total daily dose <4g. Pain was assessed using the Roland-Morris Pain Scale (RMPS), Oswestry Disability Index (OST), and a Visual Analog Scale (VAS) at baseline and again at Day 28. On Days 7 and 14, VAS and patient breakthrough medication usage were evaluated. Patients randomized to the ibuprofen group were given 400 mg/day in the morning with a two-capsule dose of placebo (L-alanine) twice daily. In the Theramine group, subjects were given a two-capsule dose of Theramine twice daily and a single capsule of placebo in the morning. The group receiving combination therapy (Theramine and ibuprofen) received a two-capsule dose of Theramine twice daily and 400 mg of ibuprofen in the morning. On the RMPS, the percent change from Baseline to Day 28 was statistically significant (P<0.01), showing improved pain ratings for both the Theramine and the combined Theramine with ibuprofen groups compared with the ibuprofen alone group (0).

Tenocin Lotion: 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: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: Terocin lotion is a topical analgesic containing the following active ingredients: Capsaicin, Lidocaine, Menthol and Salicylate. According to the Chronic Pain Medical Treatment Guidelines, the use of topical analgesics is largely experimental with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, $\hat{I}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, \hat{I}^3 agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Topical lidocaine, in the formulation of a dermal patch (Lidoderm[®]) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. According to MTUS (July 18, 2009) Chronic Pain Medical Treatment Guidelines. Therefore the request for topical Terocin lotion is not medically necessary. The request for Tenocin Lotion is not medically necessary or appropriate.

Synovacin, 500mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine as well as an online search through the website Medline.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50. Decision based on Non-MTUS Citation online search through the website Medline-Plus for glucosamine sulfate.

Decision rationale: According to on the Chronic Pain Medical Treatment Guidelines, a naturally occurring chemical found in the human body especially in the fluid that is around joints, is recommended as an option 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). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, double blind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease modification. (Pavelka, 2002) The Glucosamine

Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. Differences in results originate from the differences in products, study design and study populations. Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacod