

Case Number:	CM13-0026343		
Date Assigned:	11/22/2013	Date of Injury:	07/09/2010
Decision Date:	02/04/2014	UR Denial Date:	08/26/2013
Priority:	Standard	Application Received:	09/18/2013

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. 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:

The claimant is a 45-year-old female who began employment with [REDACTED] on March 16, 2009, as a warehouse worker. Her job duties consisted of, but were not limited to, placing products on pallets, wrapping pallets, scanning items, and loading and unloading boxes. She was required to lift and carry up to 53 pounds. She worked in a standing position during her shift, eight hours per day, five days per week. On July 9, 2010, she was lifting several boxes of merchandise, after being assigned a heavy workload. She recalls lifting a 25 pound box when she felt a sharp pain in her low back with pain radiating to her hips. As she felt the pain, she dropped the box on the desk. She reported the injury to her employer and was referred for medical attention. She was initially evaluated at the industrial clinic. X-rays of the low back were taken. Medications were prescribed. She was referred to physical therapy for several weeks. She was released to work with modified duties of no lifting, pushing or pulling over ten pounds, and no repetitive bending, stooping and squatting. She returned to work and states her restrictions were not honored. She was made to work regular duties, but on her own she limited herself from lifting over ten pounds. She continued to return for follow ups and was eventually referred for an MRI. After having the MRI scan of the low back performed, she was found to have abnormalities and was referred to pain management for epidural injections. In December 2010, she was evaluated by [REDACTED], pain management specialist, and was recommended an epidural injection. She had one lumbar epidural injection administered, which provided temporary relief. On March 16, 2011, she returned to [REDACTED] and was recommended another epidural injection but she refused. In turn, he deemed her permanent and stationary. He released her from care. Some time passed and she then sought medical attention from [REDACTED]. Her treatment with [REDACTED] consist

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 50 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Section Page(s): 76-78, 84, 92.

Decision rationale: According to Chronic Pain Medical Treatment Guidelines, page 84, section regarding the use of Tramadol states: "A recent Cochrane review found that this drug decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. There are no long-term studies to allow for recommendations for longer than three months. (Cepeda, 2006) Similar findings were found in an evaluation of a formulation that combines immediate-release vs. extended release Tramadol. Adverse effects included nausea, constipation, dizziness/vertigo and somnolence. (Burch, 2007)". The guideline further states in page 92 of 127 that "opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs".) CA-MTUS (Effective July 18, 2009) page 78 to 79 of 127, section on On-Going Management of Opioids. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drugtaking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose.. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of m

TGHot 180 gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 110-111.

Decision rationale: TGHOT is a compound topical analgesic consisting of Tramadol/Gabapentin/Menthol/Camphor/Capsaicin 8/10/2/0.05%) cream. Per the California MTUS, 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, $\hat{1}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, $\hat{1}^3$ 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. 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, Gabapentin is not recommended for topical use, since there is no peer-reviewed literature to support use.. Therefore the request for TGHOT 180 gram cream is not medically necessary based on the above guideline.

Glucosamine #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Section Page(s): 50.

Decision rationale: The California MTUS page 50 of 127, glucosamine and chondroitin sulfate items are 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, doubleblind 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. 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. Base on the foregoing, glucosamine #60 is not medically necessary for this patient.