

Case Number:	CM13-0068479		
Date Assigned:	01/03/2014	Date of Injury:	12/18/2007
Decision Date:	08/05/2014	UR Denial Date:	12/09/2013
Priority:	Standard	Application Received:	12/19/2013

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 Occupational Medicine 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:

The patient is a 61-year-old male who has filed a claim for left-sided facial neuralgia associated with an industrial injury date of December 18, 2007. Review of progress notes indicates improved post-traumatic headache, lumbar spine pain, peripheral neuropathy in the bilateral lower extremities, and left great toe onychomycosis. Patient also complains of left-sided facial neuralgia, cervical spine pain, and bilateral knee pain. Examination of the chest, cardiovascular system, and abdomen were unremarkable. Examination of the extremities showed mild bilateral lower extremity pitting edema; and left great toenail growth with discharge through porous thickened nail and mild, malodorous, green/blue discoloration. Of note, patient was diagnosed with adult onset diabetes mellitus and hypertension in 2009. Blood glucose levels are controlled most of the time, and average daily blood pressure is at 160s/90s. Treatment to date has included topical analgesics and facial surgical repair of laceration. Patient is also on antihypertensives, oral hypoglycemic medications, aspirin, and Lovaza. A utilization review from December 09, 2013 denied the requests for Lovaza 4g; topical cream (capsaicin 0.025%, flurbiprofen 20%, tramadol 15%, menthol 2%, camphor 2%); nutritional counseling; topical cream 240g (flurbiprofen 20%, tramadol 20%); and urine drug screen. Reasons for denial were not submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION OF LOVAZA 4G: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Dietetic Association, Disorders of lipid metabolism. Evidence-based nutrition practice guideline; March 2011, pg. 149.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA (Lovaza omega-3-acid ethyl esters).

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. According to FDA, Lovaza is indicated as an adjunct to diet to reduce triglyceride levels in adults with very high (>500mg/dL) triglyceride levels. Therapy should be withdrawn in patients who do not have an adequate response after 2 months of treatment. Lipid-regulating agents should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. Patient has been on this agent since at least February 2013. Mention of laboratory results dated May 22, 2013 showed triglyceride level at 260mg/dL, and there is no documentation that the patient has tried and failed non-drug methods for triglyceride control. The criteria for using this medication have not been met. The requested quantity is not specified. Therefore, the request for 1 prescription of Lovaza 4g is not medically necessary.

PRESCRIPTION OF TOPICAL CREAM CAPSAICIN 0.025%, FLURBIPROFEN 20%, TRAMADOL 15%, MENTHOL 2%, CAMPHOR 2%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines : Capsaicin, topical; Topical Analgesics; Tramadol (Ultram, Ultram ER; generic available in immediate release tablet) Page(s): 28, 111-113, 93-94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical salicylates.

Decision rationale: As noted on page 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is little to no research as for the use of flurbiprofen in compounded products. Tramadol is indicated for moderate to severe pain, but there is no guideline evidence supporting topical use. Regarding the Capsaicin component, CA MTUS Chronic Pain Medical Treatment Guidelines on page 28 states that topical Capsaicin is only recommended as an option when there is failure to respond or intolerance to other treatments; with the 0.025% formulation indicated for osteoarthritis. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. There is no documentation of trial and failure of or intolerance to conventional pain medications. Also, certain components of this compound are not supported for topical application. There is no discussion concerning the

need for variance from the guidelines. Therefore, the request for topical cream (capsaicin 0.025%, flurbiprofen 20%, tramadol 15%, menthol 2%, camphor 2%) is not medically necessary.

PRESCRIPTION OF TOPICAL CREAM 240G, FLURBIPROFEN 20%, TRAMADOL 20%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Tramadol (Ultram, Ultram ER; generic available in immediate release tablet) Page(s): 111-113, 93-94.

Decision rationale: As noted on page 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is little to no research as for the use of flurbiprofen in compounded products. Tramadol is indicated for moderate to severe pain, but there is no guideline evidence supporting topical use. There is no documentation of trial and failure of or intolerance to conventional pain medications. Also, the components of this compound are not supported for topical application. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for topical cream 240g (flurbiprofen 20%, tramadol 20%) is not medically necessary.

NUTRITIONAL COUNSELING: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes chapter, Lifestyle (diet & exercise) modifications.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, dietary and exercise modifications are essential for all patients with diabetes. This patient has multiple co-existing conditions including diabetes mellitus, controlled with medications; gastroesophageal reflux disease, more controlled with medication; uncontrolled hypertension; hyperlipidemia; and proteinuria secondary to hypertension and diabetes. Lifestyle change is a very important aspect in the management of these conditions. The patient has been advised to follow a low acid, low fat, low cholesterol, low glycemic, and low sodium diet. However, there is no documentation regarding the patient's compliance and failure, to necessitate a formal nutritional counseling session at this time. Therefore, the request for nutritional counseling is not medically necessary.

ONE URINE DRUG SCREEN: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, STEPS TO AVOID MISUSE.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines : Opioids, On-Going Management Page(s): 78.

Decision rationale: As stated on page 78 of the California MTUS Chronic Pain Medical Treatment Guidelines, urine drug screens are recommended as an option to assess order use or presence of illegal drugs and as ongoing management for continued opioid use. There is no mention of current medication regimen involving controlled substances such as opioids, or of evidence to suspect illegal drug use in this patient. Several urine drug screens performed in 2013 showed negative results. Therefore, the request for urine drug screen is not medically necessary.