

<b>Case Number:</b>	CM14-0093160		
<b>Date Assigned:</b>	07/25/2014	<b>Date of Injury:</b>	05/23/2011
<b>Decision Date:</b>	09/22/2014	<b>UR Denial Date:</b>	06/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2014

### 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 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 58-year-old male who has submitted a claim for pain in joint, upper arm associated with an industrial injury date of May 23, 2011. The medical records from 2013 through 2014 were reviewed, which showed that the patient complained of shoulder pain described as a constant tingling sensation that felt like "broken bone", worse with activity, without radiation and associated with occasional numbness. Patient had multiple episodes of elevated fasting blood glucose and random glucose. The treatment to date has included sling with shoulder immobilizer, medications (Metformin and Topiramate), diabetic diet, exercise, LidoPro Cream and a trial of TENS unit. Patient was also for shoulder surgery. A utilization review from June 12, 2014 denied the request for Metformin 1000mg #60, LidoPro Cream, TENS unit and Topiramate 1000mg #60. The request for the TENS unit was denied because the treatment plan regarding the request was not elucidated and the prior use of the unit was not adequately documented. The request for LidoPro Cream was denied because the guidelines do not support its use. The request for Topiramate was denied because there was no documented improvement from prior Topiramate use and the patient did not present with physical findings of neuropathic pain during the time of the request. The request for Metformin 1000 mg was denied because inadequate information was provided.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Metformin 1000mg #60:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment for workers' Compensation, Online Edition Chapter Diabetes.

**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, Metformin.

**Decision rationale:** The California MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the ODG was used instead. According to ODG, Metformin is recommended as a first-line treatment for type 2 diabetes to decrease insulin resistance. It can be used as monotherapy or in combination with other anti-diabetic agents. It is effective in decreasing fasting and post-prandial glucose concentrations, and has beneficial effects on weight, lipid profile, and fibrinolysis. Patient has been on this medication since at least March 6, 2014. Patient had significantly elevated blood sugar and was scheduled for left shoulder surgery. As a result the request for Metformin 1000mg #60 was certified by Utilization Review on 6/12/14. Continuation of this medication, with ongoing blood sugar monitoring and medication dose adjustments, is necessary in this patient for optimal blood sugar control. Therefore, the request for Metformin 1000mg #60 was medically necessary.

**Lidopro Cream:** 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 Page(s): 111-113.

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines pages 111-113 state that topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The guidelines also state that any compounded product that contains at least one drug or drug class that is not recommended is also not recommended. In this case, the patient requested for LidoPro Cream. LidoPro topical ointment contains capsaicin in 0.0325%, Lidocaine 4.5%, menthol 10% and methyl salicylate 27.5%. Regarding the Menthol component, California 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. The California MTUS states on page 105 that salicylate topicals are significantly better than placebo in chronic pain. The California MTUS Chronic Pain Medical Treatment Guidelines on page 28 states that topical Capsaicin is only recommended as an option when there was failure to respond or intolerance to other treatments. The guideline states there is no current indication that an increase over a 0.025% formulation of capsaicin would provide any further efficacy. Lidocaine is not recommended for topical applications. Furthermore, the compounded medication contains Lidocaine and capsaicin in 0.0325% formulation that are not recommended for topical use. Therefore the request for LidoPro cream bottles was not medically necessary.

**TENS Unit:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS  
Page(s): 114-116.

**Decision rationale:** According to California MTUS Chronic Pain Treatment Guidelines, TENS is not recommended as a primary treatment modality. A trial of one-month home-based TENS may be considered as a noninvasive conservative option. It should be used as an adjunct to a program of evidence-based functional restoration. A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function. In this case, patient has undergone unspecified sessions of TENS treatment. However, the duration, frequency, and functional outcome were not documented to support the continuation of TENS treatment per guidelines requirement. The request likewise failed to specify the body part to be treated, intended duration of treatment period, and if the device is for rental or purchase. Therefore, the request for TENS unit is not medically necessary.

**Topiramate 1000mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-21.

**Decision rationale:** Pages 16 to 21 of the California MTUS Chronic Pain Medical Treatment Guidelines state that Topiramate has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. A good response to the use of anti-epileptic drugs (AEDs) has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. Lack of response may be a 'trigger' for switching to a different first-line agent or combination therapy. Outcomes with at least 50% reduction of pain are considered good responses. In this case, the patient has been on Topiramate since at least March 2014. It is unclear whether the use of this medication has resulted in functional benefits such as decreased pain scores and increased ability to perform activities of daily living. Specific reduction in pain using a pain scale is significant in order to document good response from Topamax, per the guidelines noted above. Continued use is contingent upon efficacy. Therefore, the request for Topiramate 1000mg #60 is not medically necessary.