MAXIMUS Federal Services

| Case Number: | CM14-0053316 | | |
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| Date Assigned: | 07/07/2014 | Date of Injury: | 09/06/2011 |
| Decision Date: | 09/22/2014 | UR Denial Date: | 03/13/2014 |
| Priority: | Standard | Application Received: | 04/21/2014 |

## 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 Medicine and is licensed to practice in Florida. 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 injured worker is a 31-year-old female who reported an injury on 09/06/2011 due to an unknown mechanism. Diagnoses were cervical disc protrusion, cervical musculoligamentous injury, cervical radiculopathy, thoracic musculoligamentous injury, left shoulder internal derangement, left shoulder myoligamentous injury, right shoulder internal derangement, right shoulder sprain/strain, right elbow sprain/strain, right lateral epicondylitis, left wrist internal derangement, left wrist sprain/strain, right wrist internal derangement, right wrist sprain/strain, and sleep disturbance. Past treatments were chiropractic treatment, acupuncture, physiotherapy, cortisone injection to bilateral shoulders, and multiple cervical ESIs. Diagnostic studies were an EMG for the upper extremities that was normal. Surgical history was not reported. Physical examination on 03/11/2014 revealed multiple complaints of pain throughout the body. The average pain was rated a 7/10. Examination of the cervical spine revealed a +3 tenderness to palpation of the cervical paravertebral muscles. There was muscle spasm of the cervical paravertebral muscles. Thoracic spine had a +3 tenderness to palpation of the paravertebral muscles. Bilateral shoulders revealed a +3 tenderness to palpation. Medications were not reported. Treatment plan was the injured worker was awaiting surgery for the right shoulder. The rationale and Request for Authorization were not submitted.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%, Tramadol 20% in Mediderm 240 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Flurbiprofen Page(s): 111, 72. Decision based on Non-MTUS Citation FDA.gov.

**Decision rationale:** The request for Flurbiprofen 20%, Tramadol 20% in Mediderm 240 grams is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institutes of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterword, or with a diminishing effect over another 2 week period. A thorough search of FDA.gov, did not indicate there was a formulation of topical tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption. The medical guidelines do not support the use of compounded topical analgesics. Therefore, the request is not medically necessary.

**Gabapentin 10%, Amitriptyline 10%, Dextromethorphan 10% in Mediderm base 240 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM,Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 113.

**Decision rationale:** The request for Gabapentin 10%, Amitriptyline 10%, Dextromethorphan 10% in Mediderm base 240 grams is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicate that gabapentin is used in the treatment of neuropathic pain. It is not recommended for the use in topical analgesics. There is no peer reviewed literature to support use by the FDA. The request for Flurbiprofen 20%, Tramadol 20% in Mediderm 240 grams is not medically necessary. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product. Clonidine is for intrathecal use and is recommended only after a short-term trial indicates pain relief in patients that are refractory to opioid monotherapy or opioids with local anesthetic. Skolnick, P. (1999) "while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy

of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined". The medical guidelines do not support the use of topical analgesics. Therefore, the request is not medically necessary.