

<b>Case Number:</b>	CM13-0041419		
<b>Date Assigned:</b>	12/20/2013	<b>Date of Injury:</b>	12/06/2008
<b>Decision Date:</b>	02/04/2014	<b>UR Denial Date:</b>	10/01/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/11/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehab, and is licensed to practice in California. He 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 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 62 year old female who reported injury on 12/06/2008. The mechanism of injury was not provided. The patient was noted to have CRPS and cervical radiculitis. The patient was noted to have pain in the right side of her neck. The patient was noted to have restricted range of motion in all planes with increased pain. The patient was noted to have muscle guarding in the cervical paraspinal and trapezius muscle groups bilaterally. The patient's diagnosis were noted to include Cervical disc with radiculitis and RSD of the upper limb. The request was made for a topical cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cream Base, Flurbiprofen 20%, tramadol 5%, clonidien .2%, cyclobenzaprine 4%, Bupivacaine 3%, 1-2 gms applied to affected area, transdermal, 3-4 times per day prn, 30 days, 360gms, refills 2:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics,cyclobenzaprine, Tramadol, clonidine, Bupivacaine Page(s): 111, 41, 82, 34-35.

**Decision rationale:** California Medical Treatment Utilization Schedule (MTUS), 2009, Chronic pain, Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. The CA MTUS indicates topical analgesics are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed....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 afterward, or with a diminishing effect over another 2-week period." This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute 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... Tramadol is not recommended as a first line therapy...California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended...Clonidine has been found to have new uses including treatment of some types of neuropathic pain. Bupivacaine has also been recommended as an alternative to clonidine" The FDA has approved Clonidine for topical use per the FDA website. A search of the FDA guidelines did not indicate Clonidine was approved for topical use. Given many of the above ingredients are not recommended nor FDA approved for usage, and there was a lack of documentation of exceptional factors to support the use, the request for Cream Base, Flurbiprofen 20%, tramadol 5%, clonidine .2%, cyclobenzaprine 4%, Bupivacaine 3%, 1-2 gms applied to affected area, transdermal, 3-4 times per day prn, 30 days, 360gms, refills 2.