

<b>Case Number:</b>	CM13-0053097		
<b>Date Assigned:</b>	03/03/2014	<b>Date of Injury:</b>	03/05/2010
<b>Decision Date:</b>	04/30/2014	<b>UR Denial Date:</b>	11/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/17/2013

### 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 Physical Medicine and Rehabilitation and is licensed to practice in Illinois. 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 60 year-old male who reported an injury on 03/05/2010 and the mechanism of injury was not provided. The injured worker has had chronic pain in the cervical region, lumbar region, shoulder and hands since his injury. The progress note from 09/11/2013 the injured worker complains of neck pain. The physical exam indicated there is reproducible positive symptomatology in the upper extremities consistent with double crushing syndrome as injured worker does have a positive palmar compression test subsequent to Phalen's maneuver. There was also a positive Tinel's consistent with carpal tunnel syndrome. The shoulder exam indicated tenderness at the shoulders anteriorly, positive Hawkins' and impingement sign and there was pain with terminal motion with limited range of motion. Hydrocodone/Apap 10/325 mg #60, compound drug ketoprofen/tramadol/lidocaine/capsaicin with three refills and compound drug flurbiprofen/cyclobenzaprine/capsaicin/Lidocaine were requested.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**HYDROCODONE/APAP 10/325MG #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 91-92,78.

**Decision rationale:** The California MTUS guidelines recommend hydrocodone/apap for moderate to moderately severe pain and only used for a short time. Guidelines also note there should be on-going review of the 4A's to include anagelsia, activities of daily living, adverse side effects and aberrant drug-taking behaviors to support conntiued use. The medical documentation fails to indicate how long the injured has been on the hydrocodone/apap 10/325 mg and if it is decreasing his pain and improving his function. The documentation failed to address whether the injured worker was experiencing any side effects from the medication. The request also does not indicate the frequency the medication was prescribed for. Therefore, the request for hydrocodone/apap 10/325 mg #60 is non-certified.

**COMPOUNDED DRUG: FLURBIPROFEN/CYCLOBENZAPRINE/  
CAPSAICIN/LIDOCAINE:** 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 111, TOPICAL CYCLOBENZAPRINE PAGE 113, LIDOCAINE, PAGE 112 AND TOPICAL.

**Decision rationale:** California 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. 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. 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. Regarding the use of Lidocaine, Lidoderm is the only formulation of topical Lidocaine that is FDA approved. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The documentation provided failed to indicate the injured worker had not responded to or was intolerant to other treatments to support the use of Capsaicin. Therefore, with the above documentation the request for compound drug flurbiprofen/cyclobenzaprine/capsaicin/lidocaine is not medically necessary.

**COMPOUNDED DRUG: KETOPROFEN/TRAMADOL/ LIDOCAINE/CAPSAICIN  
WITH THREE REFILLS:** 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 CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, TOPICAL ANALGESICS, TOPICAL CYCLOBENZAPRINE, LIDOCAIN.

**Decision rationale:** California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of Ketoprofen, it is not currently FDA approved for a topical application. 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, which is not recommended as a first line therapy. Regarding the use of Lidocaine, Lidoderm is the only formulation of topical Lidocaine that is FDA approved. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The documentation provided failed to indicate the injured worker had not responded to or was intolerant to other treatments to support the use of Capsaicin. With the above documentation, the current request for compound drug ketoprofen/tramadol/lidocaine/capsaicin with three refills is not medically necessary.