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| <b>Case Number:</b>   | CM14-0182897 |                              |            |
| <b>Date Assigned:</b> | 11/07/2014   | <b>Date of Injury:</b>       | 04/21/1998 |
| <b>Decision Date:</b> | 03/06/2015   | <b>UR Denial Date:</b>       | 10/21/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 11/03/2014 |

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 sustained a work related injury on April 21, 1998, noted to be diagnosed with carpal tunnel syndrome and bilateral upper extremity problems due to repetitive job duties. The injured worker was noted by the UR Physician to be status post right carpal tunnel release in 1998 and 2001, status post left carpal tunnel release in 2001 and 2013, and status post left cubital tunnel release and medial epicondyle debridement in 2012. Copies of the surgical reports were not included in the documentation provided. The injured worker's previous conservative treatments were noted to have included physical therapy, chiropractic care, cortisone injection to the shoulder, and oral and transdermal medications. The Primary Treating Physician's report dated April 10, 2014, noted the injured worker with 90% improvement from a cortisone injection to the right shoulder. The Physician noted the right shoulder with pain and tenderness over the anterior lateral deltoid, mild to moderate acromioclavicular joint tenderness, limited range of motion, and positive impingement maneuver. The left elbow was noted to have a well healed incision from previous surgery with residual medial epicondylar tenderness and full range of motion. The bilateral wrists and hands were noted to have well healed carpal tunnel release scars with residual tenderness and full range of motion. The Physician noted the diagnoses as bilateral chronic lateral epicondylitis, bilateral carpal tunnel syndrome status post multiple surgeries for each, and internal derangement of bilateral shoulders. The Primary Treating Physician's report dated October 9, 2014, noted the injured worker with persistent symptoms, with physical examination noted to show shoulders impingement, and tender epicondyles. The Physician requested authorization for Baclofen 2%, Flurbiprofen 5%, Acetyl-L-Carnitine 15% 180

grams. On October 21, 2014, Utilization Review evaluated the request for Baclofen 2%, Flurbiprofen 5%, Acetyl-L-Carnitine 15% 180 grams, citing the MTUS Chronic Pain Medical Treatment Guidelines, and [http://www.leginfo.ca.gov/pub/11-12/bill/asm/ab\\_0351-0400/ab\\_378\\_bill\\_20110908\\_amended\\_sen\\_v94.html](http://www.leginfo.ca.gov/pub/11-12/bill/asm/ab_0351-0400/ab_378_bill_20110908_amended_sen_v94.html). The UR Physician noted that topical analgesics were primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants had failed, and that the available report did not provide evidence that the injured worker had failed a trial of antidepressants and anticonvulsants in the past. The guidelines were noted to state that if any compounded medication contains at least one drug that is not recommended, the medication is not recommended. The UR Physician noted that the guidelines did not recommend Baclofen in a topical form, and that there was no peer-reviewed literature to support the use of topical Baclofen. The UR Physician noted that based on the lack of guidelines support for individual components of the topical cream, the use of the medication was not supported, therefore, the request for Baclofen 2%, Flurbiprofen 5%, Acetyl-L-Carnitine 15% 180 grams was recommended as non-certified. The decision was subsequently appealed to Independent Medical Review.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Baclofen, Flurbiprofen, Acetyl-Carnitine 180g:** 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 based on Non-MTUS Citation AETNA guidelines <http://google2.fda.gov/search?q=Acetyl+L-carnitine&client> The U.S. Food and Drug Administration (FDA)

**Decision rationale:** The patient presents with right shoulder pain and tenderness over the anterior lateral deltoid and mild to moderate acromioclavicular joint tenderness. The request is for BACLOFEN / FLURBIPROFEN/ ACETYL-L-CARNITINE 180GM for the treatment of bilateral carpal tunnel syndrome. There is limited range of motion and positive impingement maneuver. Per progress report dated 10/09/14, the request is for the treatment of bilateral carpal tunnel syndrome. Patient's diagnosis included bilateral chronic lateral epicondylitis, bilateral carpal tunnel syndrome, and internal derangement, bilateral. Patient is permanent and stationary. MTUS has the following regarding topical creams (page 111, chronic pain section), Topical analgesics: Nonsteroidal anti-inflammatory agents (NSAIDs): The efficacy and clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. 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 an NSAID indicated for peripheral joint arthritis/tendinitis. MTUS Guidelines states, there is currently one phase 3 study of baclofen-amitriptyline-ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer review literature to support the use of topical Baclofen. MTUS, page 111, further states that if one of the compounded topical products is not recommended, The

MTUS, ACOEM and ODG guidelines are silent with regards to ACETYL-L-CARNITINE. Per AETNA guidelines, <http://google2.fda.gov/search?q=Acetyl+L-carnitine&client>, the U.S. Food and Drug Administration (FDA) conducted an inspection of Acetyl L-Carnitine and found that the dietary supplements have been prepared, packed, or held under conditions that do not meet CGMP regulations for dietary supplements. In this case, Baclofen, a muscle relaxant, is currently not recommended in topical formulation. Furthermore, the patient does not present with osteoarthritis as indicated by MTUS Guidelines for Flurbiprofen. Therefore, the request IS NOT medically necessary.