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| <b>Case Number:</b>   | CM14-0055640 |                              |            |
| <b>Date Assigned:</b> | 07/09/2014   | <b>Date of Injury:</b>       | 03/13/2013 |
| <b>Decision Date:</b> | 09/16/2014   | <b>UR Denial Date:</b>       | 03/27/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 04/24/2014 |

### 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:

Patient is a 40-year-old male who has submitted a claim for lumbar sprain/strain and lumbar radiculopathy associated with an industrial injury date of 3/13/2013. Medical records from 2013 to 2014 were reviewed. Patient complained of constant severe low back pain, associated with stiffness and weakness. Aggravating factors included heavy lifting, sitting, standing, walking, and bending. Physical examination of the lumbar spine showed tenderness, muscle spasm, and restricted range of motion. Treatment to date has included physical therapy, use of a TENS unit, and medications such as naproxen, Protonix, Flexeril, compound creams, and tramadol/L-carnitine (since November 2013). Utilization review from 3/27/2014 denied the requests for Tramadol-L-Carnitine 40-125mg QTY: 90; Capsaicin 0.025 percent, Flurbiprofen 20 percent, Tramadol 15 percent, Menthol 2 percent, Camphor 2 percent 10gm; Capsaicin 0.025 percent, Flurbiprofen 20 percent, Tramadol 15 percent, Menthol 2 percent, Camphor 2 percent 240gm; and Flurbiprofen 15 percent, Cyclobenzaprine 02 percent 240gm. Reasons for denial were not made available.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol-L-Carnitine 40-125mg QTY: 90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94, 76-78. Decision based on Non-MTUS Citation Official Disability Guidelines Pain (last updated 03/18/2014).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Section, Medical Food and Compound Drugs.

**Decision rationale:** As stated on page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The ODG states that L-carnitine is a medical food, which may be used if there is distinctive nutritional requirement. In addition, ODG states that compound drugs are not approved by the FDA. In this case, patient has been on tramadol/L-carnitine since November 2013. There is no discussion concerning the need to provide tramadol with a compounded L-carnitine. Furthermore, there is no evidence that patient has a nutritional deficiency necessitating intake of medical food. There is no documented rationale for this request. The medical necessity has not been established. Therefore, the request for Tramadol-L-Carnitine 40-125mg QTY: 90 is not medically necessary.

**Capsaicin 0.025 percent, Flurbiprofen 20 percent, Tramadol 15 percent, Menthol 2 percent, Camphor 2 percent 10gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines Pain (updated 03/18/2014) Compound drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin; Topical Analgesics Page(s): 28-29; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. In addition, there is little to no research as for the use of flurbiprofen in compounded products. The topical formulation of tramadol does not show consistent efficacy. Regarding the Menthol component, CA 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 guidelines do not address camphor. CA MTUS Chronic Pain Medical Treatment Guidelines identifies on page 28 that topical Capsaicin is only recommended as an option if 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. In this case, the patient has been prescribed topical cream as adjuvant therapy to oral medications. However, the requested compounded product contains flurbiprofen and tramadol, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. Therefore, the request for Capsaicin 0.025 percent, Flurbiprofen 20 percent, Tramadol 15 percent, Menthol 2 percent, Camphor 2 percent 10gm is not medically necessary.

**Capsaicin 0.025 percent, Flurbiprofen 20 percent, Tramadol 15 percent, Menthol 2 percent, Camphor 2 percent 240gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines Pain (updated 03/08/2014) Compound drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin; Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. In addition, there is little to no research as for the use of flurbiprofen in compounded products. The topical formulation of tramadol does not show consistent efficacy. Regarding the Menthol component, CA 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 guidelines do not address camphor. CA MTUS Chronic Pain Medical Treatment Guidelines identifies on page 28 that topical Capsaicin is only recommended as an option if 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. In this case, the patient has been prescribed topical cream as adjuvant therapy to oral medications. However, the requested compounded product contains flurbiprofen and tramadol, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. Therefore, the request for Capsaicin 0.025 percent, Flurbiprofen 20 percent, Tramadol 15 percent, Menthol 2 percent, Camphor 2 percent 240gm is not medically necessary.

**Flurbiprofen 15 percent, Cyclobenzaprine 02 percent 240gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines Pain (updated 03/08/2014) Compound drugs.

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. In addition, there is little to no research as for the use of flurbiprofen in compounded products. Cyclobenzaprine is not recommended for use as a topical analgesic. In this case, the patient has been prescribed topical cream as adjuvant therapy to oral medications. However, the requested compounded product contains flurbiprofen and cyclobenzaprine, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended.

Therefore, the request for Flurbiprofen 15 percent, Cyclobenzaprine 02 percent 240gm is not medically necessary.