

Case Number:	CM14-0147275		
Date Assigned:	09/15/2014	Date of Injury:	10/30/1998
Decision Date:	10/15/2014	UR Denial Date:	08/08/2014
Priority:	Standard	Application Received:	09/10/2014

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 Management, and is licensed to practice in Tennessee. 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 55-year-old female who has submitted a claim for cervical spine discopathy, chronic rotator cuff syndrome, chronic lumbar radiculitis, and right carpal tunnel syndrome associated with an industrial injury date of 10/13/1998. Medical records from 2014 were reviewed. The patient complained of neck pain radiating to the right upper extremity. Physical examination of the cervical spine showed tenderness and muscle spasm. Impingement test was positive bilaterally. Both Tinel's and Phalen's tests were positive at the wrist bilaterally. Treatment to date has included chiropractic care, acupuncture, and medications. Utilization review from 8/8/2014 denied the request for 81 capsules of Tramadol/L-Carnitine 40/125mg because of no clear indication and there was no evidence of improvement from previous use; and denied the requests for 1 container of compound medication (Gabapentin 10%, Cyclobenzaprine 1% and Lidocaine 5%) 180mg and 1 contained of compound medication (Capsaicin .0375%, Flurbiprofen 5%, Tramadol 6.5%, Menthol 2% and Camphor 2%) 180gm because of lack of published studies concerning its efficacy and safety.

IMR ISSUES, DECISIONS AND RATIONALES

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

81 CAPSULES OF TRAMADOL/L-CARNITINE 40/125MG: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20-9792.26, TRAMADOL 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, 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 81 capsules of Tramadol/L-Carnitine 40/125mg is not medically necessary.

**1 CONTAINER OF COMPOUND MEDICATION (GABAPENTIN 10%,
CYCLOBENZAPRINE 1% AND LIDOCAINE 5%) 180MG:** 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 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. CA MTUS does not support the use of opioid medications and Gabapentin in a topical formulation. Cyclobenzaprine is not recommended for use as a topical analgesic. Topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains Gabapentin, Cyclobenzaprine, and Lidocaine, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the request for 1 container of compound medication (Gabapentin 10%, Cyclobenzaprine 1% and Lidocaine 5%) 180mg is not medically necessary.

**1 CONTAINED OF COMPOUND MEDICATION (CAPSAICIN .0375%,
FLURBIPROFEN 5%, TRAMADOL 6.5%, MENTHOL 2% AND CAMPHOR 2%)
180GM:** Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, pages 28-29; Topical Analgesics, pages 111-113 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. 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. Topical NSAIDs formulation is only supported for Diclofenac in the California MTUS. 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. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains Capsaicin 0.037% formulation, Flurbiprofen, and Tramadol, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the request for 1 contained of compound medication (Capsaicin .0375%, Flurbiprofen 5%, Tramadol 6.5%, Menthol 2% and Camphor 2%) 180gm is not medically necessary.