

<b>Case Number:</b>	CM14-0147357		
<b>Date Assigned:</b>	09/15/2014	<b>Date of Injury:</b>	12/15/2010
<b>Decision Date:</b>	10/28/2014	<b>UR Denial Date:</b>	08/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas. 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 52 year-old female who is reported to have a date of injury of 12/15/10. Per the 08/07/14 the injured worker remains symptomatic. She is noted to have positive Finklesteins and Tinel's tests bilaterally. There is tenderness and decreased cervical range of motion secondary to pain. Her Axial compression test is positive. There is pain along the medial and lateral joint lines of the right knee. A request was made for compounded medications which contain Gabapentin 10%/Cyclobenzaprine 2%/Lidocaine 5% and Capsaicin 0.0375% Flurbiprofen 5%/Tramadol 6.5%/Menthol 2%/Camphor 2%. These requests were determined not medically necessary on 08/18/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**GABAPENTIN 10%/CYCLOBENZAPRINE 2%/LIDOCAINE 5%:** 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): 111-114. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Compounded Medications

**Decision rationale:** The request for a compounded medication which contains Gabapentin 10%/Cyclobenzaprine 2%/Lidocaine 5% is not medically necessary. The submitted clinical records indicate the injured worker has chronic pain secondary to workplace injuries. The California Medical Treatment Utilization Schedule, the Official Disability Guidelines and US FDA do not recommend the use of compounded medications as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. This compound contains: Gabapentin 10% and Cyclobenzaprine 2% which have not been approved by the FDA for transdermal use. Any compounded product that contains at least one drug (or drug class) that is not recommended and therefore not medically necessary.

**CAPSAICIN 0.0375%/FLURBIPROFEN 5%/TRAMADOL 6.5%/MENTHOL 2%/CAMPBOR 2%:** 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): 111-114.

**Decision rationale:** The request for a compounded medication which contains Capsaicin 0.0375%/Flurbiprofen 5%/Tramadol 6.5%/Menthol 2%/Camphor 2% is not medically necessary. The submitted clinical records indicate the injured worker has chronic pain secondary to workplace injuries. The California Medical Treatment Utilization Schedule, the Official Disability Guidelines and US FDA do not recommend the use of compounded medications as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. This compound contains: Flurbiprofen 5% and Tramadol 6.5% which have not been approved by the FDA for transdermal use. Any compounded product that contains at least one drug (or drug class) that is not recommended and therefore not medically necessary.