

<b>Case Number:</b>	CM14-0129033		
<b>Date Assigned:</b>	08/18/2014	<b>Date of Injury:</b>	08/18/2011
<b>Decision Date:</b>	09/16/2014	<b>UR Denial Date:</b>	07/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/13/2014

### 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:

The patient is a 49-year-old male who has submitted a claim for right ankle and foot strain/sprain status post surgery associated with industrial injury date of 8/18/2011. Medical records from 2013 to 2014 were reviewed. The patient complained of intermittent right ankle pain, rated 7/10 in severity. Physical examination showed well-healed surgical scars over the right ankle with tenderness and positive drawer's sign. He was able to toe heel walk and tandem walk. Range of motion of the right ankle was restricted on all planes. There was grade 4/5 muscle weakness of right ankle muscles. Sensory and reflexes were intact. Treatment to date has included right ankle surgery, activity restrictions, physical therapy, and medications such as hydrocodone/APAP, naproxen, omeprazole, tramadol, orphenadrine, and topical products. Utilization review from 7/15/2014 denied the request for Compound Cream Medications-#1-Flurbiprofen 20% Tramadol 20% In Mediderm Base 30 Grams, Amitriptyline 1.0% Dexamethorphan 1.0 Do Gabapentin 10% In Mediderm Base 30 Grams, #2-Flurbiprofen 20% because of limited 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:

**Compound Cream Medications-#1-Flurbiprofen 20% Tramadol 20% In Mediderm Base 30 Grams, Amitriptyline 1.0% Dexamethorphan 1.0 Do Gabapentin 10% In Mediderm Base 30 Grams, #2-Flurbiprofen 20% T: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation <http://www.fda.gov/ICECO/Enforcementactions/warningletters/2008/ucm1048048.htm>.

**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. The topical formulation of tramadol does not show consistent efficacy. Amitriptyline is a tricyclic antidepressant considered first-line agents, but there is no discussion regarding topical application of this drug. Dextromethorphan is not addressed in the guidelines. Gabapentin is not recommended for use as a topical analgesic. In this case, topical product was prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains Flurbiprofen, tramadol, amitriptyline and gabapentin that 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 Compound Cream Medications-#1-Flurbiprofen 20% Tramadol 20% In Mediderm Base 30 Grams, Amitriptyline 1.0% Dexamethorphan 1.0 Do Gabapentin 10% In Mediderm Base 30 Grams, #2-Flurbiprofen 20% is not medically necessary.