

<b>Case Number:</b>	CM14-0105557		
<b>Date Assigned:</b>	07/30/2014	<b>Date of Injury:</b>	12/26/2012
<b>Decision Date:</b>	10/20/2014	<b>UR Denial Date:</b>	06/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/08/2014

### 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 Family Practice 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 injured worker is a 48 year old female who sustained an injury on 12/26/12 when a 15lb object struck the injured worker in the right shin area. The injured worker had been followed for ongoing complaints of low back pain. Prior treatment has included acupuncture treatment as well as LINT. As of 06/05/14, the injured worker was noted to have ongoing loss of lumbar range of motion with tenderness to palpation. Pain was severe at 9/10 on the VAS. Prior urine drug screen results were inconsistent with prescribed Hydrocodone and Cyclobenzaprine. The injured worker's medications were denied on 06/30/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **Flurbiprofen 20 percent/Tramadol 20 percent in Mediderm Base 210gms.: 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 06/10/14), Compound drugs, Criteria for Compound Drugs.

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

**Decision rationale:** In regards to the use of a compounded topical medication that includes Flurbiprofen and Tramadol, this reviewer would not have recommended this medication as

medically necessary based on the clinical documentation provided for review and current evidence based guideline recommendations. The CA MTUS Chronic Pain Treatment Guidelines and US FDA note that the efficacy of compounded medications has not been established through rigorous clinical trials. The FDA requires that all components of compounded topical medication be approved for transdermal use. This compound contains Flurbiprofen and Tramadol which are not approved for transdermal use. The clinical documentation provided did not indicate that there were any substantial side effects with the oral version of the requested medication components. Therefore, this compound cannot be supported as medically necessary.

**Gabapentin 10 percent/Dexamethorphan 10 percent/Amitriptyline 10 percent in Mediderm base 30 grams.: 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 (ODG) Pain (updated 06/10/14), Compound drugs, Criteria for Compound drugs.

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

**Decision rationale:** In regards to the use of a compounded topical medication that includes Gabapentin, Dexamethorphan, and Amitriptyline, this reviewer would not have recommended this medication as medically necessary based on the clinical documentation provided for review and current evidence based guideline recommendations. The CA MTUS Chronic Pain Treatment Guidelines and US FDA note that the efficacy of compounded medications has not been established through rigorous clinical trials. The FDA requires that all components of compounded topical medication be approved for transdermal use. This compound contains Gabapentin, Dexamethorphan, and Amitriptyline which are not approved for transdermal use. The clinical documentation provided did not indicate that there were any substantial side effects with the oral version of the requested medication components. Therefore, this compound cannot be supported as medically necessary.

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