

<b>Case Number:</b>	CM14-0142864		
<b>Date Assigned:</b>	09/10/2014	<b>Date of Injury:</b>	01/11/2012
<b>Decision Date:</b>	10/20/2014	<b>UR Denial Date:</b>	08/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/03/2014

### 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 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 50 year old female who is reported to have sustained injuries to her left knee as a result of the trip and fall occurring on 01/11/12. The submitted clinical record consists of an MRI of the left knee dated 07/15/14. This report indicates the injured worker has tricompartmental osteoarthritic changes manifested by joint space narrowing and osteophyte formation. There is a moderate to large joint of effusion seen. There is increased signal in the anterior and posterior forms of the medial meniscus. The record does not contain any additional clinical data. The record contains a utilization review determination dated 08/25/14. Requests for compounded medications which contain Flurbiprofen /Tramadol 20/15 percent 210 gram and Cyclobenzaprine/Tramadol/ Flurbiprofen 2/10/20 percent 210 gram were non-certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%, Tramadol 15% 210gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Creams. Decision based on Non-MTUS Citation Official Disability Guidelines, Compound Topical Analgesic Creams

**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 and Food and Drug Administration (FDA)

**Decision rationale:** The request for a compounded medication Flurbiprofen/Tramadol 20/15 percent 210 gram is not supported as medically necessary. The California Medical Treatment Utilization Schedule, the Official Disability Guidelines and Food and Drug Administration (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/ Tramadol 20/15 percent 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 is not recommended. Therefore, this request is not medically necessary.

**Cyclobenzaprine 2%, Tramadol 10%, Flurbiprofen 20% 210gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Creams. Decision based on Non-MTUS Citation Official Disability Guidelines, Compound Topical Analgesic Creams

**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 and Food and Drug Administration (FDA).

**Decision rationale:** The request for Cyclobenzaprine/Tramadol/Flurbiprofen 2/10/20 percent 210 gram is not medically necessary. The California Medical Treatment Utilization Schedule, the Official Disability Guidelines and Food and Drug Administration (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 Cyclobenzaprine/Tramadol/ Flurbiprofen 2/10/20 percent 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 is not recommended. Therefore, this request is not medically necessary.