

Case Number:	CM14-0021910		
Date Assigned:	05/09/2014	Date of Injury:	08/09/2013
Decision Date:	07/10/2014	UR Denial Date:	02/13/2014
Priority:	Standard	Application Received:	02/21/2014

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 Orthopedic Surgery 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 38 year old female who sustained work related injuries on 08/09/13. On the date of injury she was stacking eggs and tripped over a box on the floor. She reported that she tried to hold herself up on a cart with her right hand which caused her low back to twist as she fell. She described immediate pain in the left shoulder and low back. She subsequently was seen by a physician and referred for physical therapy. She underwent two cortisone injections in the low back and left shoulder. She reported low back pain radiating into the right lower extremity. MRI of the lumbar spine dated 09/13/13 noted L5-S1 posterior disc bulge which compromised the exiting nerve roots. On physical examination she had 5-/5 strength in the right EHL. Straight leg raise was reportedly positive on the right. Current medications included Tramadol 150mg, Naprosyn 550mg, Xanax 1mg, Prilosec 20mg, and she utilized topical creams which contained Ketoprofen, Gabapentin, and Tramadol. Utilization review determination dated 02/13/14 non-certified the request for a compounded medication containing Tramadol and Cyclobenzaprine, compounded medication containing Cyclobenzaprine and Gabapentin Flurbiprofen and Tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

**RETROSPECTIVE COMPOUNDED MEDICATION: TRAMADOL
POWDER/CYCLOBENZAPRINE POWDER: Upheld**

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Compounded Medications.

Decision rationale: The request for compounded medication containing Tramadol powder, Tramadol, and Cyclobenzaprine powder is non-certified as medically is not medically necessary. Per California Medical Treatment Utilization Schedule (CA MTUS), the Official Disability Guidelines (ODG), and US FDA, does 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: Tramadol and Cyclobenzaprine 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.

RETROSPECTIVE COMPOUNDED MEDICATION: CYCLOBENZAPRINE POWDER, GABAPENTIN POWDER, FLURBIPROFEN POWDER AND TRAMADOL POWDER:
Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Compounded Medications.

Decision rationale: The request for compounded medication containing Cyclobenzaprine powder, Gabapentin powder, Flurbiprofen powder, and Tramadol powder is non-certified. Per California Medical Treatment Utilization Schedule (CAMTUS), the Official Disability Guidelines (ODG) 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: Cyclobenzaprine, Gabapentin and Flurbiprofen 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.