

Case Number:	CM14-0037867		
Date Assigned:	06/25/2014	Date of Injury:	01/09/2002
Decision Date:	07/29/2014	UR Denial Date:	03/13/2014
Priority:	Standard	Application Received:	03/31/2014

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 California and Nevada. 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 47 year old male who sustained work related injuries on 01/09/02. Mechanism of injury was not described. The claimant is status post posterior lumbar interbody fusion from L4 through S1 with subsequent hardware removal. The records suggested that this surgery occurred in 2006. The injured worker has chronic low back pain radiating into the bilateral lower extremities. Serial physical examinations indicated that the patient was motor, sensory and reflex intact. The injured worker had reduced lumbar range of motion and myofascial tenderness. The current medication profile for the injured worker included hydrocodone tramadol and aspirin. The claimant had grossly elevated pain levels despite being on oral medications. Utilization review determination dated 03/10/14 non-certified the requests for gaba/keto/lido 5% and amitriptyline/tramadol/dextromethorphan.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gaba/Keto/Lido 5% (gabapentin 6%/ketoprofen 20%/lidocaine HCL 6.15%): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111.

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 Gaba/Keto/Lido 5% (gabapentin 6%/ketoprofen 20%/lidocaine HCL 6.15%) is not medically necessary. 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 and Ketoprofen 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 and is therefore not medically necessary.

Amitramadol-DM (amitriptyline 4%/tramadol 20%/dextromethorphan 10%) transderm:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111.

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 Amitramadol-DM (amitriptyline 4%/tramadol 20%/dextromethorphan 10%) transderm is not medically necessary. 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: amitriptyline 4%, tramadol 20% and dextromethorphan 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, the entire compound is not recommended and therefore not medically necessary.