

<b>Case Number:</b>	CM14-0021429		
<b>Date Assigned:</b>	06/11/2014	<b>Date of Injury:</b>	03/12/2011
<b>Decision Date:</b>	07/14/2014	<b>UR Denial Date:</b>	01/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/20/2014

### 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 Preventative Medicine, has a subspecialty in Occupational 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 injured on 03/12/11. The injured worker was helping a 300 pound person up from a table. Onset of symptoms following the injury is not documented. The injured worker has received extensive physical therapy, anti-inflammatory medications, antispasmodics, pain medication, and anticonvulsant medication. Examination on 01/07/14 noted the injured worker had complaints of back and leg pain with weakness that caused her to fall. She reported that the pain was getting worse. Gait was stiff and guarded with restricted lumbar flexion. Muscle testing on the left was reported to be 4/5 in the quadriceps, hamstrings, gastrocnemius, and extensor hallucis longus. Lumbar magnetic resonance imaging (MRI) on 12/06/13 showed a L3-4 3mm disc protrusion encroaching on the thecal sac and left foramen with compromise of the left nerve root. At the L4-5 level, there was 5mm of anterolisthesis with a disc protrusion and extrusion causing canal stenosis and compromise of the left lateral recess and nerve root. A 3mm disc bulge was present at the L5-S1 level with encroachment of the epidural fat and foramen with no nerve root compression. Electrodiagnostic studies (EMG) Nerve Conduction Velocity(NCV) testing on 11/13/13 showed chronic active bilateral L4-5 radiculopathy greater on the left. Reexamination on 02/18/14 showed continued back pain with bilateral hip pain. Lumbar flexion remained limited and painful. Bilateral straight leg raise testing was now positive at 30 degrees. Sensation was decreased in L4 to S1 dermatomes. Motor weakness was reported the same. The request was for decompression and fusion of L4-5. Topical cream (Ketoprofen 30 grams, Gabapentin 12 grams, Tramadol 30 grams). The request for decompression and fusion of L4-5 is medically appropriate and necessary based on the clinical evidence of L5 radiculopathy. MRI evidence of spondylolisthesis and disc herniation and failure of conservative treatment.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **DECOMPRESSION AND FUSION OF L4-L5:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 307.

**Decision rationale:** The request for a topical cream, Ketoprofen 30gm, Gabapentin 12 gm, and Tramadol 30 gm is not supported medically necessary. California Medical Treatment Utilization Schedule (MTUS), the Official Disability Guidelines (ODG) and United States 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: gabapentin and tramadol 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.

### **TOPICAL CREAM (KETOPROFEN 30GM, GABAPENTIN 12GM, TRAMADOL 30GM):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The request for a topical cream, Ketoprofen 30gm, Gabapentin 12 gm, and Tramadol 30 gm is not supported medically necessary. California Medical Treatment Utilization Schedule (MTUS), the Official Disability Guidelines (ODG) and United States 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: gabapentin and tramadol 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.