

<b>Case Number:</b>	CM15-0131643		
<b>Date Assigned:</b>	07/17/2015	<b>Date of Injury:</b>	11/18/2013
<b>Decision Date:</b>	08/13/2015	<b>UR Denial Date:</b>	06/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/07/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Emergency Medicine

### 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 44 year old male, who sustained an industrial injury on November 18, 2013. He reported injury to his low back. The injured worker was diagnosed as having sprain/strain right knee and sprain/strain lumbar spine with right lower extremity radiculopathy and erectile dysfunction. Treatment to date has included diagnostic studies, functional capacity evaluation, medication and injection. The injured worker was noted to have 50-60% improvement after his initial lumbar epidural steroid injection with lasting benefit. On December 3, 2014, the injured worker complained of low back pain radiating to the right leg. The treatment plan included x-ray, medication, aquatic therapy, cane and a follow-up visit. On June 2, 2015, Utilization Review non-certified the request for Gabacyclotram 180 mg, citing California MTUS Guidelines, Official Disability Guidelines and other additional guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gabacyclotram 180mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids-criteria for use; Weaning of Medications; Non-steroidal anti-inflammatory drugs (NSAIDs) gastrointestinal (GI) symptoms and cardiovascular risk; Benzodiazepines; Carisoprodol (Soma); Topical Salicylate; Topical Analgesics Page(s): 76-80; 124; 68-69; 24; 29;

105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 13th Edition (Web), 2015, Pain-Salicylate topicals; US National Institutes of Health (NIH) National Library of Medicine (NLM) PubMed, 2014 (<http://www.ncbi.nlm.nih.gov/>).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter, Medical Food.

**Decision rationale:** The requested Gabacyclotram 180mg, is not medically necessary. Neither the ACOEM Guidelines nor California MTUS addresses nutraceuticals, but per Official Disability Guidelines (ODG), Pain (Chronic) Chapter, Medical Food, medical foods are addressed and the definition "is a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for specific dietary management of a disease or condition for a distinctive nutrition or requirement based on recognized scientific principles or established by medical evaluation. To be considered, the product must at a minimum meet the following criteria: (1) The product must be food for oral or tube feeding. (2) The product must be labeled for dietary management of a specific medical disorder, disease, or condition for a distinctive nutritional requirement. (3) The product must be used under medical supervision. The injured worker has low back pain radiating to the right leg. The treating physician has not documented any specific dietary diseases or conditions nor nutritional requirements, requiring nutritional supplements. The treating physician has not provided sufficient evidence-based, peer-reviewed and nationally-recognized medical literature in support of this supplement. The criteria noted above not having been met, Gabacyclotram 180mg is not medically necessary.