

<b>Case Number:</b>	CM14-0063574		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	06/01/2013
<b>Decision Date:</b>	09/10/2014	<b>UR Denial Date:</b>	04/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/06/2014

### 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 Occupational Medicine, and is licensed to practice in California. 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:

This is a 36-year-old male with a 6/1/13 date of injury. The mechanism of injury was not noted. According to a progress report dated 6/20/14, the patient had no significant pain complaints. He had some mild low back pain, but nothing significant. The patient's pain score was 3/10 and since his last visit, his pain score has averaged 5/10. Without pain medications, the patient's pain score is 5/10 and with pain medications, his pain score is 3/10. Objective findings: limited to vital signs. Diagnostic impression: lumbar radiculopathy left sacroiliac dysfunction, pain-related insomnia. Treatment to date: medication management, activity modification, lumbar ESI. A UR decision dated 4/24/14 denied the requests for Percura and Flurbiprofen/Tramadol ointment. Regarding Percura, scientific and guideline support for the greater efficacy of Percura compared with FDA approved neuropathic agents is not found. Regarding Flurbiprofen/Tramadol ointment, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine. The addition of topical Tramadol is of unproven efficacy and per MTUS guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Percura, two tabs po bid:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Other Medical Treatment Guideline, or Medical Evidence:  
[http://ptloffice.com/downloads/marketing/Percura\\_Package\\_Insert\\_AUG\\_2013.pdf](http://ptloffice.com/downloads/marketing/Percura_Package_Insert_AUG_2013.pdf).

**Decision rationale:** CA MTUS does not address this issue. According to an online search, Percura is a specially formulated Medical Food product, consisting of a proprietary blend of amino acids in specific proportions, for the dietary management of the metabolic processes associated with pain, inflammation, and loss of sensation due to peripheral neuropathy. The formulation consists of nonessential and essential amino acid L-Arginine HCL, L-Histidine HCL, L-Glutamine, L-Serine, L-Lysine, L-Ornithine, Acetyl L-Carnitine, L-Tyrosine, the nonstandard amino acid Gamma Aminobutyric Acid, Choline Bitartrate, Glucose, Inositol, Griffonia Extractgriffonia simplicifolia (95% 5-HTP) , and Creatinine. However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. It is documented that the provider has prescribed Percura for the patient's dysesthesias and paresthesias. Guidelines do not support the use of medical foods unless it is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. There is no documentation that the patient has a deficiency of the amino acids comprising Percura. Therefore, the request for Percura, two tabs po bid was not medically necessary.

**Flurprofen/Tramadol Ointment:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 25, 28, 111-113.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in anything greater than a 0.025% formulation, Baclofen, Boswellia Serrata Resin, and other muscle relaxants, and Gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Guidelines do not support the use of Flurbiprofen or Tramadol in a Topical formulation. A specific rationale identifying why this compound medication would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Flurbiprofen/Tramadol Ointment was not medically necessary.