

<b>Case Number:</b>	CM13-0009012		
<b>Date Assigned:</b>	03/24/2014	<b>Date of Injury:</b>	02/17/2011
<b>Decision Date:</b>	04/22/2014	<b>UR Denial Date:</b>	07/10/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/09/2013

### 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 Physical Medicine & Rehabilitation, has a subspecialty in Pain 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:

The injured worker is a 47-year-old male with a date of injury of February 17, 2011. The injured worker carries diagnoses of low back pain, lumbar radiculopathy, and neurogenic claudicating. The disputed issues are a request for 2 different compounded formulations. One compounded formulation consists of Flurbiprofen, Lidocaine, and Amitryptiline. The other consists of Gabapentin, Cyclobenzaprine, and Tramadol. These were requested on date of service the 8th 2013. A utilization review on July 10, 2013 had noncertified these requests. The rationale for the non certification of a compounded cream containing the topical NSAID is that the guidelines do not recommend topical NSAID for the hip, shoulder, or spine. The rationale for the non certification of the second compounded cream was that there was no evidence for and muscle relaxants such as Cyclobenzaprine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 PRESCRIPTION FOR FLUR/LIDO/AMIT 20/5/5/ 240GMS BETWEEN 5/8/2013 AND 5/8/2013: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

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

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify the following regarding topical Analgesics: "Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\beta$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic<sup>®</sup> (fentanyl transdermal system).]" One of the components of this compounded formulation is flubiprofen, which is a topical NSAID. The Chronic Pain Medical Treatment Guidelines states the following regarding topical NSAIDs: "Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." This injured worker has primarily low back pain, lumbar radiculopathy, and is status post lumbar spinal surgery as documented in a primary treating physician's progress report on July 22, 2013. Given the guidelines, the request for topical NSAID is not indicated in this body region and the entire formulation is recommended for noncertification.

**1 PRESCRIPTION FOR GABA/CYCLO/TRAM 10/6/10 240GMS BETWEEN 5/8/2013 AND 5/8/2013: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

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

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify the following regarding topical Analgesics: "Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local

anesthetics, antidepressants, glutamate receptor antagonists,  $\hat{I}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\hat{I}^3$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic<sup>®</sup> (fentanyl transdermal system).] In the case of this compounded formulation, one of the active ingredients is gabapentin. On page 113 of the Chronic Pain Medical Treatment Medical Guidelines, the following is stated: "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." Therefore, topical gabapentin is recommended for non-certification, and the entire formulation is not recommended.