

<b>Case Number:</b>	CM13-0008861		
<b>Date Assigned:</b>	05/14/2014	<b>Date of Injury:</b>	07/24/2012
<b>Decision Date:</b>	06/10/2014	<b>UR Denial Date:</b>	07/31/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/08/2013

### 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 Family Practice, has a subspecialty in Pain Management 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 patient is a 49 year old female claimant who sustained a work injury on 7/24/12 involving the mid and low back. She had a diagnosis of spondylolisthesis of the L4-L5 region, L4-L5 radiculopathy and thoracic strain. The patient had undergone physical therapy and epidural steroid injections for pain control. In addition, the treating physician had prescribed her topical analgesic compounds that included Flurbiprofen, Gabapentin, Capsaicin .0375%, Gabapentin 10%, Ketoprofen and Ketamine for several months to minimize pain and gastrointestinal side effects or oral medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUNDED MEDICATION: FLURBIPROFEN POWDER, ETHOXY LIQ DIGYCOL, PLO TRANSDERMAL CREAM) (1) ONE MONTH SUPPLY:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines, regarding Topical Analgesics, states, "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." The MTUS guidelines also state, "Flurbiprofen is a topical NSAID. Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjoldal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations." In this case, the claimant has been on Flurbiprofen for several months for back pain. It is not indicated beyond 2 weeks for arthritis, and neither is it indicated for chronic back pain. Therefore, the request for compounded medication, Flurbiprofen Powder, Ethoxy Liq Digycol, Plo Transdermal Cream, (1) one month supply, is not medically necessary and appropriate.

**COMPOUNDED MEDICATION: CYCLOBENZAPRINE, GABAPENTIN, CAPSAICIN POWDER, ETHOXY LIQ DIGYCOL, PLO TRANSDERMAL CREAM (1) ONE MONTH SUPPLY: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines, "Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Other muscle relaxants (Cyclobenzaprine): There is no evidence for use of any other muscle relaxant as a topical product. The MTUS Guidelines also states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore the request for compounded medication: Cyclobenzaprine, Gabapentin, Capsaicin Powder, Ethoxy Liq Digycol, Plo Transdermal Cream (1) one month supply, is not medically necessary and appropriate.

**COMPOUND MEDICATION: KETOPROFEN POWDER, KETAMINE HCL POWDER, ETHOXY LIQ DIGYCOL, PLO TRANSDERMAL CREAM (1) ONE MONTH SUPPLY:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines, "Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical Ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined." The MTUS Guidelines also states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore the request for compound medication: Ketoprofen Powder, Ketamine Hcl Powder, Ethoxy Liq Digycol, Plo Transdermal Cream (1) one month supply, is not medically necessary and appropriate.