

<b>Case Number:</b>	CM14-0015514		
<b>Date Assigned:</b>	02/28/2014	<b>Date of Injury:</b>	12/12/1994
<b>Decision Date:</b>	12/23/2014	<b>UR Denial Date:</b>	01/28/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/06/2014

### 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 Physical Medicine and 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 52 year-old male with a date of injury of December 12, 1994. The patient's industrially related diagnoses include cervical spine sprain/strain, cervical and lumbar radiculopathy, post-traumatic arthritis of the left clavicle and acromioclavicular joint, left carpal tunnel syndrome, lumbar spondylosis, neuropathic pain of the left upper extremity and bilateral lower extremities, gastritis secondary to medications, cervicogenic headaches, status post brain injury, anxiety, and depression. The disputed issues are prescriptions for flurbiprofen 20% gel, ketoprofen 20%/ ketamine 10% gel, and gabapentin 10%/ cyclobenzaprine 10%/ capsaicin 0.0375% gel. A utilization review determination on 1/28/2014 had non-certified these requests. The stated rationale for the denial was "Claimant has complaints of pain to the neck, thoracic, and lumbar areas. MD is requesting compound medication. However, compound delivery systems are not generally FDA approved as the mechanism by which the drugs are delivered and its efficacy has not been extensively studied. This appears to be off label usage of these medications."

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20% gel:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section on Chronic Pain, Subsection Under Medication - Compound Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Regarding the request for topical Flurbiprofen 20% gel, guidelines state that topical NSAIDs are.

**Decision rationale:** Regarding the request for topical Flurbiprofen 20% gel, guidelines state that topical NSAIDs are recommended for short-term use. Oral NSAIDs contain significantly more guideline support, provided there are no contraindications to the use of oral NSAIDs. Within the documentation available for review, the treating physician indicated that the injured worker had developed gastritis confirmed by endoscopy secondary to his prolonged use of medication and was prescribed Prilosec along with diet changes. In a progress report dated 10/29/2013, the treating physician indicated that concurrent H. pylori infection in addition to the use of anti-inflammatory agents precipitated his dyspeptic symptoms. Based on the documentation and the injured worker's risk for gastrointestinal events with oral NSAID use, the request for Topical Flurbiprofen 20% is medically necessary.

**Ketoprofen 20% / Ketamine 10% gel:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section on Chronic Pain, Subsection Under Medication - Compound Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113 of 127..

**Decision rationale:** Regarding the request for topical Ketoprofen 20%/ Ketamine 10% gel, Chronic Pain Medical Treatment Guidelines state that ketamine is only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Furthermore, the guidelines state: "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000)" Given this, this request is not medically necessary. In the submitted documentation available for review, the requesting physician has identified that the injured worker has significant neuropathic pain complaints supported by the diagnosis of neuropathy of bilateral upper and lower extremities. However, the injured worker was taking Neurontin orally at the time of the request and Neurontin is an anti epilepsy drug (AED) used to treat neuropathic pain. Furthermore, the guidelines do not recommend ketoprofen for topical application. In light of these issues, the request for Ketoprofen 20%/ Ketamine 10% gel is not medically necessary.

**Gabapentin 10% / Cyclobenzaprine 10% / Capsaicin 0.0375%:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section on Chronic Pain, Subsection Under Medication - Compound Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113 of 127..

**Decision rationale:** Regarding the request for topical Gabapentin 10%/ Cyclobenzaprine 10%/ Capsaicin 0.0375% gel, Chronic Pain Medical Treatment Guidelines states that topical muscle relaxants are not recommended as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxants as a topical product. Gabapentin is also not recommended because there is no peer-reviewed literature to support its use. The guidelines further state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Given these guidelines, the request for Gabapentin 10%/ Cyclobenzaprine 10%/ Capsaicin 0.0375% gel is not medically necessary.