

<b>Case Number:</b>	CM13-0030445		
<b>Date Assigned:</b>	11/27/2013	<b>Date of Injury:</b>	11/29/2010
<b>Decision Date:</b>	01/24/2014	<b>UR Denial Date:</b>	09/21/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology, 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 physician 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 53- year-old male who reported injury on 11/29/2010. The mechanism of injury was not provided. The patient was noted to have complaints of low back pain a 5-6/10 with 2+ trigger point to lumbar spine. Diagnosis were noted to include protrusion lumbosacral spine at L3-L4 and L5-S1 with radiculitis/radiculopathy and lumbar spine myofascial pain syndrome. The request was made for Flurbiprofen 20 between 8/28/2013 and 8/28/2013, 1 prescription for Gabapentin/Cyclobenzaprine/Capsaicin 10/10/0.0375% 120gm between 8/28/2013 and 8/28/2013 and 1 prescription for Ketamine/Ketoprofen 10/20%, 120gm between 8/28/2013 and 8/28/2013.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20 between 8/28/2013-8/28/2013: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72, 111.

**Decision rationale:** Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. The California Chronic Pain Medical Treatment Guidelines indicates topical analgesics are "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...Topical Non-Steroidal Anti-Inflammatory Drugs 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." This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. As the topical Flurbiprofen is not supported by the FDA or the treatment guidelines, the request is not certified as medically necessary.

**Gabapentin, Cyclobenzaprin, Capsaicin, 10/10/.0375% 120mg between 8/28/2013 and 8/28/2013: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41,111,112,113.

**Decision rationale:** California Chronic Pain Medical Treatment Guidelines states that topical analgesics are "Largely experimental in use with few randomized control trials to determine efficacy or safety. .Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy... Gabapentin: Not recommended do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended". Given the above and that all of the medications in the compound are not recommended, along with a lack of documentation to support non-adherence to guideline recommendations, the request for 1 prescription for Gabapentin/Cyclobenzaprin/Capsaicin 10/10/0.0375% 120gm between 8/28/2013 and 8/28/2013 is not medically necessary or appropriate.

**for Ketamine/Ketoprofen 10/20%, 120mg between 8/28/2013 and 8/28/2013: Upheld**

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

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

**Decision rationale:** California Medical Treatment Utilization Schedule (MTUS), 2009, Chronic pain, Page 111, indicates Topical analgesics are largely experimental in use with few randomized

controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application. The compound also included topical Ketamine which is under study and is only recommended in treatment of neuropathic pain which is refractory to all primary and secondary treatment. The guidelines do not recommend Ketoprofen and as such the use of the compound is not medically necessary or appropriate.