

<b>Case Number:</b>	CM15-0014850		
<b>Date Assigned:</b>	02/02/2015	<b>Date of Injury:</b>	10/28/2010
<b>Decision Date:</b>	05/13/2015	<b>UR Denial Date:</b>	01/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/26/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 31-year-old female who reported injury on 10/28/2010. The mechanism of injury was not provided. The injured worker underwent a lateral release and medial ligament reconstruction and a patellar debridement on 11/24/2014. The documentation of 12/08/2014 revealed the injured worker had an initial postoperative examination of the knee. The injured worker had limited range of motion and continued to have pain. The objective findings included anterior tenderness with swelling and a limping ambulation. The injured worker underwent x-rays which revealed no increase of osteoarthritis. The treatment plan included postoperative physical therapy, a urine drug screen, and Norco 10/325 mg. There was no physician documented rationale or documentation requesting the medications for this review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Orphenadrine 50 mg, caffeine 10 mg, #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63. Decision based on Non-MTUS Citation website: <http://www.drugs.com/search.php?searchterm=caffeine&a=1>.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines recommend muscle relaxants as a second line option for the short term treatment of acute low back pain and their use is recommended for less than 3 weeks. There should be documentation of objective functional improvement. The clinical documentation submitted for review does provide evidence that the injured worker has been on this medication for an extended duration of time and there is a lack of documentation of objective improvement. The Official Disability Guidelines address compound drugs and indicate they are not recommended as a first line therapy. The California Medical Treatment Utilization Schedule and American College of Occupational and Environmental Medicine guidelines do not address caffeine, nor do the Official Disability Guidelines. As such, tertiary guidelines were sought. Per Drugs.com Caffeine is a central nervous system stimulant. The clinical documentation submitted for review failed to provide objective findings to support the necessity for a muscle relaxant. Additionally, there was a lack of documentation indicating the necessity for caffeine. The rationale was not provided. The request as submitted failed to indicate the frequency for the requested combination medication. There was lack of documentation of exceptional factors. Given the above, the request for Orphenadrine 50 mg, caffeine 10 mg, #60 is not medically necessary.

**Flurbiprofen, omeprazole 100/10 mg (quantity not specified): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS do not address compound drugs Page(s): 67-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Compound Drugs.

**Decision rationale:** The California Medical Treatment Utilization Schedule Guidelines indicate that NSAIDS are recommended for short term symptomatic relief of mild to moderate pain. There should be documentation of objective functional improvement and an objective decrease in pain. The California Medical Treatment Utilization Schedule Guidelines recommend proton pump inhibitors for injured workers at intermediate risk or higher for gastrointestinal events. They are also for the treatment of dyspepsia secondary to NSAID therapy. The Official Disability Guidelines indicate that compound drugs are not recommended as a first line therapy. There was a lack of documentation indicating a necessity for both a topical and oral form of NSAIDs. There was a lack of documentation indicating a necessity for omeprazole. There was a lack of documentation indicating the injured worker had dyspepsia. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation supporting a necessity for both and oral and topical form of an NSAID. Given the above, the request for Flurbiprofen, omeprazole 100/10 mg is not medically necessary.

**Flurbiprofen, cyclobenzaprine, menthol 20, 10, 4%, quantity not specified: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain regarding compound medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics page, Cyclobenzaprine, Salicylate Topicals Page(s): 72, 111, 41, 105.

**Decision rationale:** The California Medical Treatment Utilization Schedule 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, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. The 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. The guidelines 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. The clinical documentation submitted for review failed to provide documentation of a need for both an oral and topical NSAID. The request as submitted failed to indicate the frequency, body part, and quantity of medication being requested. Given the above, the request for Flurbiprofen, cyclobenzaprine, menthol 20, 10, 4%, quantity not specified is not medically necessary.

**Gabapentin, pyridoxine 250/10:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepileptic Drugs do not address Vitamin B Page(s): 16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Vitamin B.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines recommend anti-epilepsy medications as a first line medication for treatment of neuropathic pain. They do not address Vitamin B. As such, secondary guidelines were sought. Per the Official Disability Guidelines, B vitamins are not recommended for the treatment of chronic pain. Additionally per the Official Disability Guidelines, compound drugs are not a first line therapy. There was a lack of documentation indicating a necessity for a second line therapy. There was a lack of documentation of exceptional factors. The request as submitted failed to indicate the frequency and quantity of the medication being requested. Given the above, the request for Gabapentin, pyridoxine 250/10 is not medically necessary.

**Karatek Gel, unspecified quantity:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics, Salicylate topical Page(s): 111, 105.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The clinical documentation submitted for review failed to provide documentation of the specific components for Keratek. There was a lack of documentation of a failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency, quantity and body to be treated. Given the above, the request for Keratek Gel, unspecified quantity is not medically necessary.