

<b>Case Number:</b>	CM15-0145327		
<b>Date Assigned:</b>	08/06/2015	<b>Date of Injury:</b>	01/12/2010
<b>Decision Date:</b>	09/03/2015	<b>UR Denial Date:</b>	06/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/27/2015

### 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: New Jersey, Alabama, California  
 Certification(s)/Specialty: Neurology, Neuromuscular Medicine

### 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 64 year old female, who sustained an industrial injury on 1-12-10 Initial complaints were not reviewed. The injured worker was diagnosed as having anxiety disorder, reflex sympathetic dystrophy lower extremity. Treatment to date has included physical therapy; medications. Currently, the PR-2 notes dated 6-18-15 indicated the injured worker was in the office as a follow-up visit. Her chief complaints are of anxiety disorder and reflex sympathetic dystrophy of the lower extremity. She presented for medical re-evaluation regarding her lower extremity complex regional pain syndrome type I (RSD). She continues to complain of severe lower extremity pain that becomes worse with any weight bearing activities. She is not performing home exercise on a regular basis and her mood and sleep remain significantly dysfunctional. She has long-standing GI issues that have worsened and notes her GERD symptoms are related to medications and food. On physical examination, the provider notes her normal gait and posture. Treatment modalities suggested include psychiatry, psychology, and interdisciplinary functional restoration. He notes she shows no aberrant behavior and will return for follow-up and continued observation. The provider is requesting authorization of Zorvolex 35mg #90 with 2 refills; Omeprazole 20mg delayed release #30 with 2 refills and Biofreeze Menthol 4% topical gel #2 with 2 refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zorvolex 35mg #90 with 2 refills: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zorvolex (diclofenac). <http://www.odg-twc.com/index.html>.

**Decision rationale:** According to ODG guidelines, Zorvolex (diclofenac) "Not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects. See Diclofenac. In late 2013 FDA approved diclofenac capsules (Zorvolex, [REDACTED]) at 18-mg and 35-mg doses for the treatment of mild to moderate acute pain in adults. These dosages are 30% lower in strength than the 25-mg and 50-mg diclofenac products already on the market. The FDA also approved another lower-dose NSAID from [REDACTED], indomethacin capsules (Tivorbex). While diclofenac has potent anti-inflammatory and analgesic properties, research has linked this drug to sometimes serious adverse outcomes, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeding, and renal events (such as acute renal failure). (FDA, 2014) This new formulation of diclofenac does not present any apparent advantages versus other medications of the class. Zorvolex is pure acid versus salt in other formulations, resulting in faster dissolution using SoluMatrix Fine Particle Technology. However, it has the same side effect profile while more expensive than other NSAIDs that are available as generics. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. (FDA, 2013)" In this case, the patient has been using etodolac 300mg before switching, in February 2015, to Zorvolex. NSAIDs are not recommended for long-term chronic use. There is no clear documentation of functional improvement with previous use of Zorvolex. There is no documentation of continuous monitoring of side effects of the drug. Therefore, the request for Zorvolex 35mg #90 with 2 refills is not medically necessary.

**Omeprazole 20mg delayed release #30 with 2 refills: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 102.

**Decision rationale:** According to MTUS guidelines, Omeprazole is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. There is no

documentation in the patient's chart supporting that she is at intermediate or high risk for developing gastrointestinal events. Therefore, the request for Omeprazole DR 20mg #30 with 2 refills is not medically necessary.

**Biofreeze Menthol 4% topical gel #2 with 2 refills: Upheld**

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

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

**Decision rationale:** According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111), topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. There is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. According to ODG guidelines, "Biofreeze is recommended as an optional form of cryotherapy for acute pain. Biofreeze is a nonprescription topical cooling agent with the active ingredient menthol that takes the place of ice packs. Whereas ice packs only work for a limited period of time, Biofreeze can last much longer before reapplication. This randomized controlled study designed to determine the pain-relieving effect of Biofreeze on acute low back pain concluded that significant pain reduction was found after each week of treatment in the experimental group" ([http://www.worklossdatainstitute.verioiponly.com/odgtwc/low\\_back.htm](http://www.worklossdatainstitute.verioiponly.com/odgtwc/low_back.htm)). There is no recent documentation of failure or intolerance of oral first line drugs for pain management. Therefore, the prescription of Biofreeze Menthol 4% topical gel #2 with 2 refills is not medically necessary.