

<b>Case Number:</b>	CM15-0143598		
<b>Date Assigned:</b>	08/04/2015	<b>Date of Injury:</b>	01/30/2014
<b>Decision Date:</b>	09/08/2015	<b>UR Denial Date:</b>	07/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/24/2015

### 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: Texas, California

Certification(s)/Specialty: Family Practice

### 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 55 year old male, who sustained an industrial injury on 1-30-2014. He reported a left arm injury from a slip and fall. Diagnoses include derangement of the left shoulder, bicep muscle tear vs. left shoulder strain, impingement of the left shoulder and left bicep pain, and diabetes. Treatments to date include anti-inflammatory, opioid, and activity modification. Currently on 7/7/15, he complained of ongoing left shoulder symptoms. On 7-7-15, the physical examination documented no change in physical findings from previous visit. The patient has had normal musculoskeletal examination on 5/19/15. The plan of care included Zorvolex (Diclofenac Capsules) 35 mg, one three times a day, #90. The past medical history includes cardiovascular and diabetic conditions. The medication list includes Percocet, Norco, Nabumatone, Tramadol and Ibuprofen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription of Zorvolex 35mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, page 22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Pain (updated 07/15/15) Diclofenac.

**Decision rationale:** Request: 1 prescription of Zorvolex 35mg #90. Diclofenac belongs to a group of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs). According to CA MTUS, Chronic pain medical treatment guidelines, "Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000)." In addition as per cited guideline, diclofenac is "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients, as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%." "Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID." "It should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. In 2009, the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. (FDA, 2009) With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or no pharmacological therapy should be considered. The AGS updated Beers criteria for inappropriate medication use includes diclofenac. (AGS, 2012) Diclofenac is associated with a significantly increased risk of cardiovascular complications and should be removed from essential-medicines lists, according to a new review." Diclofenac is a NSAID. Short term use of a NSAID is considered first line treatment for musculoskeletal pain however, Diclofenac is not recommended as a first-line treatment and has increased risk of cardiovascular side effects. The past medical history includes cardiovascular and diabetic conditions. The need for Diclofenac daily, on a long term basis, with lack of documented improvement in function is not fully established. Any lab tests to monitor for side effects like renal dysfunction due to taking NSAIDS for a long period of time were not specified in the records provided. Zorvolex 35mg #90 is not medically necessary for this patient due to its risk profile.