

<b>Case Number:</b>	CM15-0209567		
<b>Date Assigned:</b>	10/28/2015	<b>Date of Injury:</b>	03/18/2014
<b>Decision Date:</b>	12/15/2015	<b>UR Denial Date:</b>	09/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/24/2015

### 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:

This is a 42 year old female with a date of injury on 3-18-14. A review of the medical records indicates that the injured worker is undergoing treatment for right foot and left upper extremity injury. The progress report dated 9-16-15 reports continued complaints of right ankle pain, left hand pain, and left foot pain. Objective findings: she walks with a significant antalgic gait with difficult weight bearing on the right foot, there is tenderness to palpation and decreased range of motion. Treatments include: medication, physical therapy, chiropractic and surgery. According to the medical records she has been taking Zorvolex since at least 4-19-15 and reports greater than 50 percent relief. The medication list include Atenolol, Nabumetone, Tylenol, and Zorvolex The patient's surgical history include right knee surgery in 1994 and right foot surgery. The patient sustained the injury due to MVA.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zorvolex 35 MG #90 with 3 Refills (Take 1 Cap 3x A Day As Needed Rx Date 9/18/15):**

Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter (updated 12/02/15) Diclofenac.

**Decision rationale:** Zorvolex (Diclofenac) is a nonsteroidal anti-inflammatory drug (NSAID) 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. 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 nonpharmacological therapy should be considered. The AGS updated Beers criteria for inappropriate medication use includes Diclofenac. 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 patient is having chronic pain and is taking Diclofenac for this injury. The detailed response to Diclofenac in terms of functional improvement is not specified in the records provided. The level of the pain with and without medications is not specified in the records provided. The need for Diclofenac on a daily basis with lack of documented improvement in function is not fully established. 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. The medical necessity of the request for Zorvolex 35 MG #90 with 3 Refills (Take 1 Cap 3x A Day as Needed Rx Date 9/18/15) is not fully established for this patient due to its risk profile.