

<b>Case Number:</b>	CM15-0160101		
<b>Date Assigned:</b>	09/01/2015	<b>Date of Injury:</b>	10/15/2009
<b>Decision Date:</b>	10/06/2015	<b>UR Denial Date:</b>	07/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/17/2015

### 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 62 year old male, who sustained an industrial injury on October 15, 2009. Medical records provided by the treating physician did not indicate the injured worker's mechanism of injury. The injured worker was diagnosed as having status post fracture injury to the right thumb, left ankle fracture, and herniated nucleus pulposus of the lumbar spine with spondylolisthesis. Treatment and diagnostic studies to date has included a medication regimen. In a progress note dated July 15, 2015 the treating physician reports complaints of pain to the low back that radiates with numbness and tingling to the bilateral lower extremities into the feet with the left worse than the right. Examination reveals decreased range of motion to the lumbar spine, increase in pain to the back with range of motion, and positive straight leg raises bilaterally. The injured worker's medication regimen included Norco and Celebrex. The injured worker's pain level was rated an 8 on a scale of 1 to 10 without the use of his medication regimen and rates the pain level a 4 to 5 on a scale of 1 to 10 with the use of his medication regimen. The treating physician also noted the injured worker to have functional improvement and an improvement in his pain with the use of his current medication regimen. The treating physician noted that the injured worker has had a history of gastroesophageal reflux disease and gastrointestinal ulcers with bleeding secondary to use of Ibuprofen, Naprosyn, Naproxen, and other medications not listed. The medication Celebrex has been tolerated by the injured worker without unwanted side effects. The treating physician requested Zorvolex 18mg with a quantity 90 noting that the injured worker was given samples of this medication and was to monitor the effects and side effects of this medication.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Zorvolex 18mg quantity 90:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic): Zorvolex (Diclofenac).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, under Zorvolex (Diclofenac).

**Decision rationale:** The patient presents on 07/15/15 with lower back pain rated 8/10, which radiates into the bilateral lower extremities. The patient's date of injury is 10/15/09. Patient has no documented surgical history directed at this complaint. The request is for Zorvolex 18mg quantity 90. The RFA is dated 07/15/15. Physical examination dated 07/15/15 reveals tenderness to palpation of the midline lumbar spine and bilateral lumbar paraspinal muscles with spasms and myofascial trigger points noted. The provider also notes positive straight leg raise test bilaterally. The patient is currently prescribed Celebrex, Norco, and Metformin. Patient is currently classified as permanent and stationary. MTUS Guidelines, Anti-inflammatory medications section, page 22 states: "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. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of anti-depressants in chronic LBP." Official Disability Guidelines, Pain Chapter, under Zorvolex (Diclofenac) has the following: 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, ██████████) 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 ██████████, 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. In regard to Zorvolex as a second-line NSAID for this patient's chronic lower back pain, the request is appropriate. Progress note dated 07/15/15 notes that this medication is being provided to the patient due to persistent denials of this patient's other NSAID medication, Celebrex. The physician states that this patient is intolerant of other first line NSAIDs, and was provided with samples of the Zorvolex and a prescription of 90 tablets (with no refills) pending reinstatement of this patient's Celebrex prescription. Given this patient's presentation and the utilization of this medication as a second-line option due to intolerance of other NSAIDs, a trial is substantiated. The request IS medically necessary.