

Case Number:	CM15-0104307		
Date Assigned:	06/08/2015	Date of Injury:	08/10/2006
Decision Date:	07/13/2015	UR Denial Date:	05/12/2015
Priority:	Standard	Application Received:	06/01/2015

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, Hawaii
 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 54 year old female, who sustained an industrial injury on 8/10/06. The injured worker has complaints of back pain. The documentation noted that the injured worker has paraspinal spasm and range of motion is reduced. The diagnoses have included lumbar spine radiculitis left leg. Treatment to date has included lumbar spine surgery, L5, S1 (sacroiliac) fusion; naprosyn; zipsor and therapy. The request was for zipsor 25 mg #60 times 1 month.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zipsor 25 mg #60 times 1 month: 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 ODG, Low back chapter, Diclofenac.

Decision rationale: The patient has ongoing low back pain which travels into the left lower extremity. The current request is for Zipsor 25mg #60 times 1 month. According to the ODG, Zipsor (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%. For a patient who has a 5% to 10% risk of having a heart attack that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID. In this nationwide cohort study the traditional NSAID diclofenac was associated with the highest increased risk of death or recurrent myocardial infarction (hazard ratio, 3.26; 95% confidence interval, 2.57 to 3.86 for death/MI at day 1 to 7 of treatment) in patients with prior MI, an even higher cardiovascular risk than the selective COX-2 inhibitor rofecoxib, which was withdrawn from the market due to its unfavorable cardiovascular risk profile. According to FDA MedWatch, post marketing surveillance of topical diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. If using diclofenac then consider discontinuing as 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. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. The current request is not medically necessary.