

<b>Case Number:</b>	CM15-0140576		
<b>Date Assigned:</b>	07/30/2015	<b>Date of Injury:</b>	02/07/2012
<b>Decision Date:</b>	08/28/2015	<b>UR Denial Date:</b>	07/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/21/2015

### 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: Internal 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 58 year old male, who sustained an industrial injury on 2-7-2012. Diagnoses have included shoulder pain and cervical pain. Treatment to date has included bilateral shoulder surgery, magnetic resonance imaging (MRI), physical therapy, chiropractic treatment and medication. According to the progress report dated 6-25-2015, the injured worker complained of pain in the bilateral shoulder region rated four out of ten with medications and eight out of ten without medications. The injured worker appeared anxious and in mild pain. Objective findings revealed restricted movement of the neck. Inspection of the right shoulder revealed atrophy and movements restricted by pain. Exam of the left shoulder revealed tenderness and restricted movement. The treatment plan was for a right shoulder sling-brace for complete rotator cuff tear. Authorization was requested for Diclofenac Sodium.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Diclofenac Sodium DR 50mg #60:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter: Diclofenac.

**Decision rationale:** 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. (McGettigan, 2011) Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID. (Varas-Lorenzo, 2011) 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. (Schjerning, 2011) According to FDA MedWatch, postmarketing 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. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. (FDA, 2011) 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 non-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. The increased risk with diclofenac was similar to Vioxx, a drug withdrawn from worldwide markets because of cardiovascular toxicity. Rofecoxib, etoricoxib, and diclofenac were the three agents that were consistently associated with a significantly increased risk when compared with nonuse. With diclofenac even in small doses it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. (McGettigan, 2013) See also NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & NSAIDs, specific drug list & adverse effects for general guidelines. See also Arthrotec (diclofenac/ misoprostol); Dyloject (diclofenac sodium injection); Flector patch (diclofenac epolamine); Pennsaid (diclofenac sodium topical solution); Zipsor (diclofenac potassium liquid-filled capsules); Zorvolex (diclofenac). In this case, the patient is already on Celebrex (a cox-2 inhibitor) and the request was to add an additional antiinflammatory medication (Diclofenac sodium). Due to the increased incidence for adverse events including cardiotoxicity, Diclofenac is not recommended as first-line treatment. Also, there is no clear indication as to why Diclofenac is being added to Celebrex. When taking both medications together the risk profile is increased. Therefore based on ODG guidelines and the evidence in this case, the request for Diclofenac Sodium DR 50 mg #60 is not medically necessary.