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| <b>Case Number:</b>   | CM15-0193664 |                              |            |
| <b>Date Assigned:</b> | 10/07/2015   | <b>Date of Injury:</b>       | 02/14/2002 |
| <b>Decision Date:</b> | 11/23/2015   | <b>UR Denial Date:</b>       | 09/23/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/01/2015 |

### 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: 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 67 year old female, who sustained an industrial injury on 02-14-2002. She has reported injury to the right wrist, right knee, and low back. The diagnoses have included multilevel lateral recess stenosis, with moderate central canal stenosis at L5-S1 on MRI of lumbar spine on 10/17/12; status post right wrist reconstruction; and right knee arthritis. Treatment to date has included medications, diagnostics, ice, heat, bracing, injection, and surgical intervention. Medications have included Naprosyn, topical compounded gel, Norco, Ultracin lotion, and Voltaren. A progress note from the treating physician, dated 08-18-2015, documented a follow-up visit with the injured worker. The injured worker reported that she is not doing well; she has complaints of severe back pain today; her pain is rated at 8 out of 10 in intensity; she is quite frustrated as her pain medication has not been authorized; she has difficulty sleeping at night and performing activities of daily living due to her pain; and she suffers from intermittent exacerbations. Objective findings included there is tenderness about the lower lumbar paravertebral musculature; ranges of motion are decreased; there is a negative sitting straight leg raise bilaterally; and strength in the lower extremities is globally intact. The provider administered an injection of Toradol intramuscularly. The patient sustained the injury due to trip and fall incident. The patient's surgical history includes right wrist surgery in 2008, and 2013 and right knee arthroscopy.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Voltaren 75mg, 1 tablet 2 times daily, #60 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications.

**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, Pain (updated 10/09/15), Diclofenac.

**Decision rationale:** Request: Voltaren 75mg, 1 tablet 2 times daily, #60 with 2 refills. 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 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." 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 patient's medication list also includes Naprosyn which is another NSAID. The response to the Naproxen without the use of Voltaren was not specified in the records provided. The rationale for the use of two NSAIDS is not specified in the records provided. The medical necessity of the request for Voltaren 75mg, 1 tablet 2 times daily, #60 with 2 refills is not fully established for this patient due to its risk profile. The request is not medically necessary.