

Case Number:	CM15-0193449		
Date Assigned:	10/07/2015	Date of Injury:	05/30/2012
Decision Date:	11/16/2015	UR Denial Date:	09/02/2015
Priority:	Standard	Application Received:	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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 47 year old female, who sustained an industrial injury on 5-30-2012. The injured worker was being treated for wrist-forearm pain and carpal tunnel syndrome. Medical records (6-11-2015 to 8-13-2015) indicate ongoing right shoulder and right wrist pain with swelling. The injured worker's right hand pain increased with grasping and repetitive motion. The medical records the subjective pain rating increased from 3 out of 10 with medication on 6- 11-2015 and 4 out of 10 without medication 3 out of 10 with medication on 7-15-2015, to 10 out of 10 without medication and 8 out of 10 with medication on 8-13-2015. Her medication helped to decrease her pain. The injured worker was attending school and looking for a part-time job. The physical exam (7-15-2015 to 8-13-2015) revealed decreased right shoulder flexion and abduction with pain. There was bilateral wrist tendon sheath tenderness and swelling, positive Finklestein's test, and decreased wrist flexion, extension, radial and ulnar bending with pain. There was a normal stability exam of the bilateral wrists. Per the treating physician (6-1-2015 report), nerve conduction studies were unremarkable. Treatment has included injections of the wrists and medications including topical pain (Voltaren Gel 1%), non-steroidal anti- inflammatory (Ibuprofen), and non-steroidal anti-inflammatory (Voltaren XR 100mg intermittently since at least 4-2015). On 8-27-2015, the requested treatments included 60 Voltaren XR 100mg (extended release). On 9-2-2015, the original utilization review non-certified a request for 60 Voltaren XR 100mg (extended release).

IMR ISSUES, DECISIONS AND RATIONALES

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

60 Voltaren XR 100mg Ext. Release: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Diclofenac.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Diclofenac.

Decision rationale: Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). The MTUS and ODG guidelines note that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. Diclofenac Sodium (Voltaren, Voltaren-XR) 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%. (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) (Schjerning, 2011) 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. With diclofenac even in small doses it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. In this case Voltaren XR has been used since at least April 2015. The ODG guidelines state that, 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) The request for continued Voltaren XR, which is not a first-line agent, would indicate relatively long-term use of this medication that has a significantly adverse cardiovascular risk profile. A first-line agent would be appropriate. The request for 60 Voltaren XR 100mg Extended Release is not medically necessary.