

<b>Case Number:</b>	CM15-0026757		
<b>Date Assigned:</b>	02/19/2015	<b>Date of Injury:</b>	11/16/2000
<b>Decision Date:</b>	04/07/2015	<b>UR Denial Date:</b>	01/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/12/2015

### 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:

This is a 57 year old female patient, who sustained an industrial injury on 11/16/2000. She sustained the injury due to cumulative trauma. The diagnoses have included left ankle pain/left toe pain, lumbosacral degenerative joint disease, cervical degenerative joint disease, right carpal tunnel syndrome, and status post right carpal tunnel release. Per the progress note dated 01/06/2015, she had complaints of continued neck, back, and left wrist pain. The treating physician reported pain continues with exacerbations and needs pain medications to reduce the pain. the physical examination revealed bilateral wrists- tenderness; cervical spine- tenderness, spasm and reduced range of motion; lumbar spine- tenderness, spasm and reduced range of motion. The medications list includes tramadol, cymbalta, lidoderm patch and zipsor. She has undergone right carpal tunnel release. She has had diagnostics studies include cervical and lumbar spine x-rays which revealed degenerative joint disease and degenerative disc disease. She has had physical therapy and injections for this injury. Utilization Review determination on 01/14/2015 non-certified the request for Zipsor 25mg #90 3 Refills citing Medical Treatment Utilization Schedule Guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zipsor 25 mg # 90 with 3 refills:** 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) Chronic Pain.

**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) Chapter:Pain(updated 03/23/15).

**Decision rationale:** Request: Zipsor 25 mg # 90 with 3 refills Anti-inflammatory medications Diclofenac Zipsor (diclofenac potassium liquid-filled capsules) Zipsor contains Diclofenac which is an NSAID. According to the cited 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)." Per the cited guidelines "Not recommend diclofenac as first line due to increased risk profile. See Diclofenac listing. Zipsor diclofenac potassium liquid-filled capsules (Xanodyne) were approved by the FDA in June 2009. (FDA, 2009) When compared with absorption characteristics of diclofenac potassium tablets, Zipsor was more rapidly absorbed after bunionectomy, which may be advantageous if rapid pain relief is required, but there were no other advantages over the tablets. (Kowalski, 2009)" Patient had chronic low back, neck and wrist pain. Therefore the use of NSAIDs as and when necessary, is medically appropriate. HOWEVER, per the cited guidelines "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." The response and failure of other NSAIDs is not specified in the records provided. In addition, patient is taking zipsor since long time. Response to pain with and without medication-zipsor is not specified in the records provided. The medical necessity of Zipsor 25 mg # 90 with 3 refills is not fully established as a first line NSAID due to its risk profile.