

Case Number:	CM15-0009724		
Date Assigned:	01/27/2015	Date of Injury:	09/06/2000
Decision Date:	03/18/2015	UR Denial Date:	01/15/2015
Priority:	Standard	Application Received:	01/16/2015

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 61 year old male patient who sustained an industrial injury on 9/8/2000. The diagnoses include displacement of cervical disc without myelopathy, cervical strain/sprain, migraine headaches, lumbar strain/sprain, lumbar degenerative disc disease, facet arthrosis, and gastrointestinal reflux disease. Per the doctor's note dated 12/23/2014, he had complaints of the pain in the neck and back and headache in the right base of the skull. He had pain to be severe rates at 8 to 9/10 without medications and at 4/10 with medications. The physical examination revealed pain with cervical compression, muscle rigidity in cervical paraspinal muscles, limited range of motion in the neck and back. The medications list includes relpax, tylenol, zorvolex, ultracet and dexilant. Other therapy for this injury was not specified in the records provided. The Utilization Review Determination on 1/15/2015 non-certified: 1. Relfax 40mg #3, citing Official Disability Guideline. 2. Zorvolex 35mg #90 citing Official Disability Guideline, non-steroidal anti-inflammatory drug. 3. Tylenol EX #120, Official Disability Guideline. 4. Dexilant 60mg #30, Official Disability Guideline.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zorvolex 35 mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, Page(s): 22. Decision based on Non-MTUS Citation Chapter: Pain (updated 02/23/15) Zorvolex (diclofenac)

Decision rationale: Request: Zorvolex 35 mg #90. Zorvolex contains diclofenac. Diclofenac is an NSAID. 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)." Patient had chronic neck and back pain and headache. Therefore use of a NSAID is medically appropriate and necessary. However, per the cited guidelines zorvolex (diclofenac) is "Not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects. See Diclofenac." While diclofenac has potent anti-inflammatory and analgesic properties, research has linked this drug to sometimes serious adverse outcomes, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeding, and renal events (such as acute renal failure). (FDA, 2014) This new formulation of diclofenac does not present any apparent advantages versus other medications of the class. Zorvolex is pure acid versus salt in other formulations, resulting in faster dissolution using SoluMatrix Fine Particle Technology. However, it has the same side effect profile while more expensive than other NSAIDs that are available as generics. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. (FDA, 2013). Therefore per the cited guidelines there is no additional advantage of zorvolex compared to other generic NSAIDs. Response to other NSAIDs like naproxen is not specified in the records provided. The medical necessity of Zorvolex 35mg #90 is not fully established as a first line NSAID due to its risk profile.

Tylenol EX #120: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Acetaminophen (APAP), Page(s): 11-12.

Decision rationale: Request: Tylenol EX #120. Tylenol extra strength (EX) contains acetaminophen 500mg. Per the cited guidelines above acetaminophen is "Recommended for treatment of chronic pain & acute exacerbations of chronic pain." Per the records provided patient had headache, neck pain and back pain with limited range of motion of the neck and back. Short term or prn use of the tylenol in this patient for acute exacerbations is considered reasonable appropriate and necessary. Therefore the request for Tylenol EX #120 is medically appropriate and necessary for this patient.

