

Case Number:	CM14-0208070		
Date Assigned:	02/02/2015	Date of Injury:	09/04/2000
Decision Date:	03/05/2015	UR Denial Date:	11/24/2014
Priority:	Standard	Application Received:	12/12/2014

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: Ohio, North Carolina, Virginia
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 54 year old male who suffered a work related injury on 09/05/00 when he twisted his left knee. Per the UR he is status post right knee arthroscopy with ACL repair and debridement and medial meniscectomy with ongoing severe knee pain and valgus deformity and severe DHD of the knee joint. Per the chiropractor's notes from 11/11/14 he reports sever right knee pain and swelling. The pain is rated at 9/10 without medications, and 4/10 with medications. The right knee is noted to be swollen on exam, with valgus deformity, excessive laxity with valgus maneuver, and crepitus on flexion. Patellar compression was noted to be very painful. Treatment regimen included Norco and Zorvolex. The Zorvolex was denied by the Claims Administrator on 11/24/14 and was subsequently appealed for independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zorvolex 35mg #90: 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), Pain

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

Decision rationale: 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. In late 2013 FDA approved diclofenac capsules (Zorvolex, Iroko Pharmaceuticals LLC) at 18-mg and 35-mg doses for the treatment of mild to moderate acute pain in adults. These dosages are 30% lower in strength than the 25-mg and 50-mg diclofenac products already on the market. The FDA also approved another lower-dose NSAID from Iroko Pharmaceuticals, indomethacin capsules (Tivorbex). 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) In this instance, Zorvolex is not medically necessary and may be quite medically inappropriate. The patient has hypertension and a history of atrial fibrillation. He may already be more prone to myocardial infarction and stroke. Diclofenac does not possess any gastrointestinal side effect risk advantages versus other NSAIDs. The submitted medical record does not specify which other NSAIDs were tried and the reasons for failure. It is not evident that a proton pump inhibitor was previously added to an alternative NSAID for dyspepsia. Therefore, Zorvolex 35mg #90 is not medically necessary.