

Case Number:	CM15-0224198		
Date Assigned:	11/20/2015	Date of Injury:	12/05/2006
Decision Date:	12/30/2015	UR Denial Date:	10/16/2015
Priority:	Standard	Application Received:	11/16/2015

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: 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 64 year old male, who sustained an industrial injury on 12-5-06. The documentation on 10-12-15 noted that the injured worker has complaints of chronic low back pain that radiates into the left buttock and down the posterior thigh to the knee. There is tenderness at L5-S1 (sacroiliac) and the left paravertebral area as well as left PSIS (posterior superior iliac spine). Straight leg raise on left produces back pain and negative on right. Postsurgical magnetic resonance imaging (MRI) demonstrated evidence of postsurgical granulation tissue 5-gibrosis at L3-L5; L3 and L4 laminectomy; L3-5-S1 (sacroiliac) one this degeneration and foraminal stenosis and L3 through L5-S1 (sacroiliac) facet arthropathy. The diagnoses have included post-laminectomy syndrome, not elsewhere classified; post-laminectomy syndrome with chronic low back pain and left sensory lumbar radiculitis and low back pain. Treatment to date has included voltaren. The original utilization review (10-16-15) non-certified the request for voltaren gel 1% 8 day supply quantity 100 with two refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren gel 1% 8 day supply quantity 100 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/ Diclofenac.

Decision rationale: Per the MTUS guidelines, Voltaren Gel 1% (diclofenac) is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, the medical records note that the injured worker is followed for back pain. According to ODG, Diclofenac is not recommended as first line due to increased risk profile. ODG notes the following, "According to FDA MedWatch, postmarketing surveillance of topical diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. If using diclofenac, 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 nonpharmacological 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. The increased risk with diclofenac was similar to Vioxx, a drug withdrawn from worldwide markets because of cardiovascular toxicity. Rofecoxib, etoricoxib, and diclofenac were the three agents that were consistently associated with a significantly increased risk when compared with nonuse. With diclofenac even in small doses, it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. (McGettigan, 2013)" The request for Voltaren gel 1% 8 day supply quantity 100 with two refills is not medically necessary and appropriate.