

Case Number:	CM14-0186748		
Date Assigned:	11/13/2014	Date of Injury:	02/11/2006
Decision Date:	12/30/2014	UR Denial Date:	10/15/2014
Priority:	Standard	Application Received:	11/04/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 46-year-old male who sustained an industrial injury on February 11, 2006. The patient is diagnosed with status post motor vehicle accident, status post lumbar spine surgery, chronic low back pain, chronic neck pain, right upper extremity radiculitis, status post right shoulder surgery, right shoulder tendinitis, anxiety, depression, and plantar fasciitis. According to September 22, 2014 progress report the patient is awaiting authorization for spine surgery. Utilization review was performed on October 15, 2014 at which time the request for Diclofenac and Omeprazole was noncertified. A letter of appeal has been submitted dated October 28, 2014 at which time it is noted there has been improvement of pain and the patient reports functional tolerance with the use of Diclofenac. With regards to omeprazole, it is noted that the patient is at high risk as he has been taking non-steroidal anti-inflammatory medications long-term and was prescribed omeprazole to prevent gastrointestinal events from the continuous use of non-steroidal anti-inflammatory medication.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac XR 100mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Inflammatory Medications Page(s): 22, 48.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, Diclofenac Sodium Page(s): 21, 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Diclofenac sodium (Voltaren®), Voltaren-XR®), Diclofenac

Decision rationale: According to evidenced based guidelines, Diclofenac is not recommended as first line due to increased risk profile. In this case, a review of the submitted medical records do not establish that the patient has failed first line NSAIDs. As per the references, 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 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 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 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) Given the concerns cited by evidence based guidelines and the FDA, and given the lack of evidence of failure of first line NSAIDs, the request for Voltaren is not supported.

Omeprazole 20mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.mayoclinic.org/healthy-living/nutrition-and-healthy-eating/expert-blog/heartburn-and-b-12-deficiency/bgp-20091051>

Decision rationale: The medical records indicate that the patient has been prescribed oral NSAIDs for an extended period of time. The medical records also indicate that further surgical

intervention may be pending. As such, the request for omeprazole may be supported at this time. However, it should be noted that per guidelines long-term use of proton pump inhibitors leads to an increased risk of hip fractures. There is also an association with long-term use of proton pump inhibitors and vitamin B12 deficiency. As such, caution is advised with regards to the long term use of this medication.