

Case Number:	CM15-0208460		
Date Assigned:	10/27/2015	Date of Injury:	01/19/2006
Decision Date:	12/15/2015	UR Denial Date:	09/29/2015
Priority:	Standard	Application Received:	10/22/2015

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 61 year old female, who sustained an industrial injury on January 19, 2006. The injured worker was diagnosed as having joint stiffness. Treatment and diagnostic studies to date has included physical therapy, status post right total knee replacement on May 01, 2012, status post right knee manipulation on December 04, 2012, and medication regimen. In a progress note dated August 28, 2015 the treating physician reports complaints of pain to the right knee that was noted to be "minimal", along with pain to the left foot, back, hip, and left knee secondary to overcompensating from the right knee. Examination performed on August 28, 2015 was revealing for soft tissue swelling to the right knee, tenderness to the right patella, tenderness to the right patella tendon, tenderness to the right lateral collateral ligament, tenderness to the right pes anserinus, the right semi-membranosus, and the right medial plica regions, decreased range of motion to the left foot, "mild" edema to the left foot, tenderness to the lateral foot, and instability to the subtalar joint of the left foot. The injured worker's medication regimen on August 28, 2015 and July 24, 2015 included Norco (since at least January 28, 2015) and Naprosyn (since at least June 12, 2015). The progress note on August 28, 2015 and July 24, 2015 noted that the injured worker's pain level can be rated up to a 7 out of 10, but did not indicate the injured worker's current pain level or the injured worker's pain level as rated on a pain scale prior to use of her medication regimen and after use of her medication regimen to indicate the effects with the use of the injured worker's medication regimen. Also, the progress note did not indicate if the injured worker experienced any functional improvement with use of her medication regimen. On August 28, 2015 the treating physician requested Norco 10-325mg with a quantity

of 90 noting current use of this medication and also requested Pennsaid 2% cream with a quantity of 1 for pain. On September 29, 2015 the Utilization Review determined the request for Norco 10-325mg with a quantity of 90 to be modified. On September 29, 2015 the Utilization Review denied the request for Pennsaid 2% cream with a quantity of 1.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids, specific drug list, Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain.

Decision rationale: The long term utilization of opioids is not supported for chronic non-malignant pain due to the development of habituation and tolerance. In this case, the medical records note that opioids have been prescribed to this injured worker for an extended period of time. Per the MTUS guidelines, in order to support ongoing opioid use, there should be improvement in pain and function. The medical records do not establish significant subjective or objective functional improvement to support the request for opioids. The progress reports noted that the injured worker's pain level can be rated up to a 7 out of 10, but did not indicate the injured worker's current pain level or the injured worker's pain level as rated on a pain scale prior to use of her medication regimen and after use of her medication regimen to indicate the effects with the use of the injured worker's medication regimen. The request for Norco is not supported and Utilization Review has allowed for modification for weaning purposes. The request for Norco 10/325mg #90 is therefore not medically necessary and appropriate.

Pennsaid 2% cream #1.00: Upheld

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

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

Decision rationale: According to ODG, Pennsaid (diclofenac sodium topical solution) is not recommended as a first-line treatment. 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 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)" As noted above, diclofenac containing agents are not recommended as first line treatment. The medical records do not establish attempt and failure at first line safer non-steroidal anti-inflammatory medication. The request for Pennsaid 2% cream #1.00 is not medically necessary and appropriate.