

Case Number:	CM15-0171382		
Date Assigned:	09/11/2015	Date of Injury:	02/01/2007
Decision Date:	10/09/2015	UR Denial Date:	08/06/2015
Priority:	Standard	Application Received:	08/31/2015

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: North Carolina
 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 58-year-old male, who sustained an industrial-work injury on 2-1-07. He reported initial complaints of bilateral knee pain. The injured worker was diagnosed as having patella-femoral chondromalacia (bilateral). Treatment to date has included medication, surgery (left knee in 1-2015), physical therapy, home exercises, ice application, and crutches. MRI results were reported on 4-10-14 demonstrated mild degenerative osteoarthritis worse in medial and patellofemoral compartments, medial meniscus tear and extrusion, patellar tendinosis with intra-substance tear in the distal and proximal tendon, low-grade sprain of medial and lateral collateral ligaments. Currently, the injured worker complains of persistent left and increased right knee pain status post left knee surgery. Medication reduced pain by 50%, improve sleep and ADL's (activities of daily living). Drug screen was consistent with prescribed medication (hydrocodone 10-325 mg). Pain was rated 2 out of 10 at best and 10 at worst and is currently at 5 on the right and 2 on the left with medications. Pain is relieved by ice. Voltaren gel increases mobility and helps 100% to reduce need for oral analgesics constantly. Physical therapy improved knee function per 7-29-15 PR-2 report with return to work on 7-31-15. Per the primary physician's progress report (PR-2) on 7-29-15, exam reveals a wide based minimally antalgic gait, hard non-mobile solid masses bilaterally at the distal patellar tendons, right greater than left, normal alignment mild swelling without erythema or effusion on the left, tenderness at the lateral joint lines, tenderness to patella and surrounding area on the left. Varus and valgus stress are painful bilaterally. Current plan of care includes Acetaminophen 500 mg QID #120 prn, Hydrocodone 10-325 mg q hs prn, Voltaren gel BID, and Glucosamine 500 mg TID. The

Request for Authorization date was 7-29-15 and requested service included Voltaren Gel 1%, QTY: 1 with 2 refills and Acetaminophen 500mg, QTY: The Utilization Review on 8-6-15 denied the request to include maximum acetaminophen dosing (not to exceed 4 gm-24 hours), tapering of opioids, and use of topical analgesics.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren Gel 1%, QTY: 1 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, "-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists," agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): 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. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most

common adverse reactions were dermatitis and pruritus. (Voltaren package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder. This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options. Therefore, criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.

Acetaminophen 500mg, QTY: 120 with 2 refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Acetaminophen.

Decision rationale: The California MTUS section on Tylenol states: Recommended for treatment of chronic pain & acute exacerbations of chronic pain. With new information questioning the use of NSAIDs, acetaminophen should be recommended on a case-by-case basis. The side effect profile of NSAIDs may have been minimized in systematic reviews due to the short duration of trials. On the other hand, it now appears that acetaminophen may produce hypertension, a risk similar to that found for NSAIDs. The patient has no contraindications to this medication in the provided medical records for review and therefore the request is medically necessary.