

Case Number:	CM15-0164967		
Date Assigned:	09/02/2015	Date of Injury:	09/19/2013
Decision Date:	10/15/2015	UR Denial Date:	07/31/2015
Priority:	Standard	Application Received:	08/21/2015

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: Physical Medicine & Rehabilitation

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 57 year old female who sustained an industrial injury on 9-19-13. Of note, several documents within the submitted medical records are difficult to decipher. The injured worker was diagnosed as having right shoulder impingement, right knee strain-sprain, foot status post-surgery. Currently, the injured worker reported pain in the right shoulder, bilateral knees and right foot. Previous treatments included medication management, injection therapy, physical therapy, and extracorporeal shockwave therapy. Previous diagnostic studies included a left knee magnetic resonance imaging (July 2015), magnetic resonance imaging of the left shoulder (July 2015), radiographic studies. Work status was noted as temporary totally disabled. The injured workers pain level was noted as 5-6 in the right shoulder and 8 out of 10 in the knee and foot. Physical examination was notable for right shoulder tender and decreased range of motion, knee tender and decreased range of motion, right foot pain, tender and decreased range of motion. The plan of care was for Flurbiprofen Capsaicin Menthol Camphor 10%-0.025%-2%-1% and Ketoprofen Cyclobenzaprine Lidocaine 10%-3%-5% 120 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Capsaicin/Menthol/Camphor 10%/0.025%/2%/1%: 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): Topical Analgesics.

Decision rationale: The patient was injured on 09/19/13 and presents with right shoulder pain, right knee pain, left knee pain, and right foot pain. The request is for FLURBIPROFEN/CAPSAICIN/MENTHOL/CAMPBOR 10%/0.025%/2%/1%. The utilization review rationale states that, "regarding Flurbiprofen, there is no documentation of failure of oral NSAIDs. Regarding capsaicin, there is no documentation that the patient is intolerant or has not responded to other treatments." The RFA is dated 06/30/15 and the patient is on temporary total disability. MTUS Guidelines, Topical Analgesics, page 111 states: "Topical Analgesics: 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. Flurbiprofen, an NSAID, is indicated for peripheral joint arthritis/tendinitis. MTUS also states that many agents are compounded for pain control including antidepressants and that there is little to no research to support their use. MTUS, page 29, Capsaicin, topical, Indications are that there are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The patient is diagnosed with right shoulder impingement, right knee strain-sprain, foot status post-surgery. Flurbiprofen is indicated for patients with joint arthritis/tendinitis, as this patient presents with her right shoulder pain and right/left knee pain. Therefore, the request is medically necessary.

Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% 120gm: 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 patient was injured on 09/19/13 and presents with right shoulder pain, right knee pain, left knee pain, and right foot pain. The request is for KETOPROFEN/CYCLOBENZAPRINE/LIDOCAINE 10%/3%/5% 120 GM. The RFA is dated 06/30/15 and the patient is on temporary total disability. MTUS Guidelines, Topical Analgesics NSAIDs, page 111 states: "Topical analgesics are largely experimental and used with few randomized controlled trials to determine efficacy or safety." 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) state: "The efficacy in clinical trials for this treatment modality

has been inconsistent and most studies are small and of short duration." Cyclobenzaprine is a muscle relaxant and is not supported for any topical formulation. MTUS page 111 states: 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. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The patient is diagnosed with right shoulder impingement, right knee strain-sprain, foot status post-surgery. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound consists of Cyclobenzaprine, Lidocaine, and Ketoprofen, neither of which are indicated for use as a topical formulation. Therefore, the requested compounded topical is not medically necessary.