

<b>Case Number:</b>	CM15-0083524		
<b>Date Assigned:</b>	05/05/2015	<b>Date of Injury:</b>	06/25/2014
<b>Decision Date:</b>	06/10/2015	<b>UR Denial Date:</b>	03/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/30/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal Medicine

### 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 49-year-old female with a reported date of injury of 06/25/2014. The diagnoses include degenerative joint disease of the left knee, osteoarthritis, contusion of the left foot/ankle, left knee sprain/strain with tear of the anterior cruciate ligament, posterior cruciate ligament, and medial/lateral meniscus, left foot sprain/strain, left ankle sprain/strain, and left heel pain. Evaluation has included MRI of the left ankle, left forefoot, and left knee. Treatments to date have included acupuncture, physical therapy, use of crutches, left knee brace, air cast for the ankle, orthotics, and medications. It was noted that the injured worker was off work from June 2014 to September 2014, and was at desk work in September 2014. Work status in December 2014 was noted as temporarily totally disabled with no modified duty available. Work status in March 2015 was noted as off work. Medications in October 2014 included tramadol, motrin, and Tylenol. The progress report dated 03/03/2015 indicates that the injured worker complained of left knee pain, left ankle pain, left foot pain with radiation to the knee with numbness and tingling, and left heel pain. The objective findings include decreased left knee flexion; tenderness to palpation of the inferior border of the left patella, lateral knee, and medial knee; decreased left ankle range of motion; tenderness to palpation of the anterior talofibular ligament in the left ankle; decreased left foot range of motion; and tenderness to palpation of the left metatarsal 1 and phalanges 1. Medications included ibuprofen, omeprazole, cyclobenzaprine, and topical creams. The treating physician requested omeprazole, Ketoprofen/PLO gel compound, Flurbiprofen/Capsaicin/Menthol/Camphor cream, and cyclobenzaprine. On 03/26/2015, Utilization Review (UR) denied the request for Omeprazole since the injured worker

was not at intermediate risk of gastrointestinal (GI) event, Ketoprofen/PLO gel compound and Flurbiprofen/Capsaicin/Menthol/Camphor cream because there was no documentation that there had been failure of first line therapy; and modified the request for cyclobenzaprine 7.5mg #60 to cyclobenzaprine 7.5mg # 30 to allow for evidence of gradual tapering. Utilization Review cited the MTUS and ODG.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Omeprazole cap 20mg #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines IODG), Proton pump inhibitors.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

**Decision rationale:** This injured worker has been prescribed ibuprofen as well as topical nonsteroidal anti-inflammatory drugs (NSAIDS) and omeprazole, a proton pump inhibitor (PPI). Per the MTUS, co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. Two topical NSAIDS were prescribed but these have been determined to be not medically necessary. As such, none of the risk factors noted are present for this injured worker. There was no documentation of GI signs or symptoms. Due to lack of specific indication, the request for omeprazole is not medically necessary.

#### **Ketoprofen/PLO gel compound: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, topical analgesics Page(s): 60, 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In this case, there was no documentation of neuropathic pain, or of failure of antidepressants or anticonvulsants. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for

lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. Ketoprofen, a nonsteroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. It has a high incidence of photocontact dermatitis. As topical ketoprofen is not FDA approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. The treating physician has not discussed the additional ingredients of this topical agent and the specific indications for this injured worker. The additional ingredients in this compounded topical product were not specified. Site of application and directions for use were not specified. The requested prescription is for an unstated quantity, and the medical records do not clearly establish the quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. As ketoprofen is not recommended, the compound is not recommended. For these reasons, the request for Ketoprofen/PLO gel compound is not medically necessary.

**FCCM cream (Flurb/Cap/Menth/Camp): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines, Chronic Pain Treatment Guidelines Medications for chronic pain, topical analgesics Page(s): 60, 111-113. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There was no documentation of neuropathic pain or of trial and failure of antidepressant or anticonvulsant medication for this injured worker. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. Flurbiprofen is a nonsteroidal anti-inflammatory drug (NSAID). Topical NSAIDs are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Capsaicin has some indications, in the standard formulations readily available without custom compounding. The MTUS also states that capsaicin is only recommended when other treatments have failed. The treating physician did not discuss the failure of other, adequate trials of conventional treatments. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The MTUS and ODG are silent with regard to menthol and camphor. They may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. Site of application and directions for use of the prescribed compounded topical medication were not specified. The requested prescription is for an unstated quantity, and the medical records do not clearly establish the

quantity. Requests for unspecified quantities of medications are not medically necessary, as the quantity may potentially be excessive and in use for longer than recommended. As multiple agents in this compounded topical product are not recommended, the compound is not recommended. As such, the request for FCMC cream (Flurb/Cap/Menth/Camp) is not medically necessary.

**Cyclobenzaprine 7.5mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine, muscle relaxants Page(s): 41-42, 63-66.

**Decision rationale:** This injured worker has chronic knee, foot, and ankle pain. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. This injured worker did not have a diagnosis of back pain or muscle spasms. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, Fexmid, Amrix) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. This injured worker has been prescribed multiple additional medications. Limited, mixed evidence does not allow for a recommendation for chronic use of cyclobenzaprine. Due to quantity requested consistent with duration of treatment in excess of the guidelines, and lack of documentation of muscle spasm or specific indication for use of muscle relaxants, the request for cyclobenzaprine is not medically necessary.