

<b>Case Number:</b>	CM15-0188609		
<b>Date Assigned:</b>	09/30/2015	<b>Date of Injury:</b>	01/12/2014
<b>Decision Date:</b>	11/12/2015	<b>UR Denial Date:</b>	08/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/24/2015

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 54 year old female who sustained an industrial injury January 12, 2014. Past history included status post left shoulder arthroscopy and decompression November 24, 2014. According to a treating physician's progress report dated July 16, 2015, the injured worker presented with complaints of left cervical, cervical, upper mid and low thoracic, left anterior knee, left buttock, left posterior leg, left posterior knee, left calf, and left; ankle, foot, hip, anterior leg, shin, pelvis, shoulder, arm and elbow pain, rated 7 out of 10. There is associated numbness and tingling in all areas related to pain. She ambulates with a walker. Only 5 pages out of 10 from this report are available for review. A primary treating physician's report dated July 21, 2015, found the injured worker with complaints of intermittent neck pain, rated 3 out of 10, worse on the left radiating to the left upper extremity and down to the wrist associated with numbness and tingling down the left arm to the fingers. There is pain over the left shoulder surgical site but the restricted range of motion has improved. The pain is localized over the left side of the cervical spine. Attempts at turning left causes severe radiating pain down to the wrist with numbness and tingling. Objective findings: C4-C7 left 2+ tenderness with myospasm palpated. Diagnoses are severe cervical spine myoligamentous sprain, strain syndrome associated with myofascial headaches and left-sided radicular symptoms. At issue, is the request for authorization for topical FCL, Meloxicam, and Prilosec. An MRI of the upper extremity with contrast dated August 14, 2015 (report present in the medical record) impression documented as; the gadolinium solution is seen both in the intra-articular space and extra-articular space of the left shoulder; this is likely related to secondary extra-articular extravasation of contrast from a

small joint, possibly related to adhesive capsulitis; no rotator cuff tear or labral tear is evident. According to utilization review dated August 27, 2015, the requests for Meloxicam 15mg #30 and Prilosec 20mg #30 are non-certified. The request for FCL (Flurbiprofen 20%- Baclofen 2%-Dexamethasone 2%-Menthol 2%-Camphor 2%-Capsaicin 0.0375%-Hyaluronic acid 0.20%) in 180 grams is non-certified.

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

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

**MED Rx 8/20/15 FCL (Flurbiprofen 20%/Baclofen 2%/Dexamethasone 2%/Menthol 2%/Camphor 2%/Capsaicin 0.0375%/Hyaluronic acid 0.20% in 180 grams): 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:** Per MTUS with regard to Flurbiprofen (p112), "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." Flurbiprofen may be indicated. Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Per MTUS p113 with regard to topical baclofen, "Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Baclofen is not indicated. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol, camphor, or hyaluronic acid. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since multiple agents are not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states, "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative

effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The request is not medically necessary.

**Meloxicam 15mg #30: 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): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** With regard to NSAIDs the MTUS CPMTG states: "Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another." "Low back pain (chronic): Both acetaminophen and NSAIDs have been recommended as first line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-by-case basis based on weighing efficacy vs. side effect profile." The documentation submitted for review indicates that the injured worker was previously treated with naproxen. There was no rationale provided as to why first-line NSAIDs were not sufficient. Medical necessity cannot be affirmed. The request is not medically necessary.

**Prilosec 20mg #30: 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): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). CPMTG guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.). Patients at

intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily); or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed. The request is not medically necessary.