

<b>Case Number:</b>	CM15-0172392		
<b>Date Assigned:</b>	09/14/2015	<b>Date of Injury:</b>	08/21/2007
<b>Decision Date:</b>	10/13/2015	<b>UR Denial Date:</b>	08/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/01/2015

### 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 61 year old male, who sustained an industrial injury on August 21, 2007. On July 31, 2015 the injured worker reported that he had access to a custom brace on the right side and a regular knee brace on the left side. He had difficulty getting up from the chair due to stiffness and discomfort. He had access to hold and cold wrap and a two-lead TENS unit. He avoided squatting, kneeling, climbing stairs and lifting. He stated that he was having so much pain on the right knee that he wants surgical intervention. On physical examination, the injured worker had tenderness along the joint line medially and a 1+ to 2+ anterior drawer test. His knee extension was 180 degrees and flexion was 125 degrees. He had instability along the left knee. An orthopedic surgeon consultation was conducted and surgery was recommended. The injured worker's medical history is significant for gastroesophageal reflux disease, diabetes, and hypertension. The injured worker was diagnosed as having internal derangement of the knee on the right status post meniscectomy medially with some laxity of the anterior cruciate ligament, internal derangement of the knee on the left status post arthroscopy followed by total joint replacement with gross instability in medial, lateral, anterior and posterior angles. His current medications include Tramadol ER 150 mg, Naproxen 550 mg, and Flexeril 7.5 mg. He has used Flexeril and Tramadol ER since at least January 23, 2015. Treatment to date has included bilateral knee surgery, therapy, cortisone injection and Hyalgan injection. A request for authorization for Tramadol ER 150 mg #30, Flexeril 7.5 mg #60 and Protonix 20 mg #60 was received on August 4, 2015. The Utilization Review physician determined on August 11, 2015

that the request for Tramadol ER 150 mg #30 be modified to Tramadol ER 150 mg #7 and that Flexeril 7.5 mg #60 and Protonix 20 mg #60 were not medically necessary.

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

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

#### **Tramadol ER 150mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Opioids, Tramadol.

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on opioids states for ongoing management: On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids: (a) If the patient has returned to work; (b) If the patient has improved functioning and pain. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) The long-term use of this

medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. There is no documented significant improvement in VAS scores for significant periods of time. There are no objective measurements of improvement in function. Therefore all criteria for the ongoing use of opioids have not been met and the request is not medically necessary.

**Flexeril 7.5mg #60:** 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): Muscle relaxants (for pain).

**Decision rationale:** The California chronic pain medical treatment guidelines section on muscle relaxants states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) (Chou, 2004) This medication is not intended for long-term use per the California MTUS. The medication has not been prescribed for the flare-up of chronic low back pain. This is not an approved use for the medication. For these reasons, criteria for the use of this medication have not been met. Therefore the request is not medically necessary.

**Protonix 20mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Proton pump inhibitors.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or a anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastro duodenal lesions. 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 (200g 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. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or cardiovascular disease. For these reasons the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore the request is not medically necessary.