

<b>Case Number:</b>	CM15-0043959		
<b>Date Assigned:</b>	03/25/2015	<b>Date of Injury:</b>	09/15/2009
<b>Decision Date:</b>	05/01/2015	<b>UR Denial Date:</b>	02/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/09/2015

### 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: 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 30 year old male who sustained an industrial injury on 09/15/09. Initial complaints and diagnoses are not available. Treatments to date include medications and a right knee brace. Diagnostic studies were not discussed. Current complaints include mid and lower back pain, radiating to the right leg and right knee pain. In a progress note dated 02/03/15, the treating provider reports the plan of care as right knee brace replacement, and medications to include Tramadol, Effexor, Omeprazole, and Trazadone. The requested treatments are for Trazadone, and Omeprazole.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of Proton Pump Inhibitors, such as Omeprazole as an adjunct when prescribing an NSAID. Typically, PPIs are considered if a patient is considered to be at intermediate or high-risk for a gastrointestinal event, such as an ulcer or a GI bleed. The MTUS recommendations are as follows; 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 an 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 gastroduodenal lesions. Recommendations for 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. In this case, the patient does not have any of the above stated risk factors and would be placed in the low-risk category for a GI event. Under these conditions, Omeprazole is not considered as a medically necessary treatment. Therefore, this request is not medically necessary.

**Trazodone 50mg #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, Pain (Acute & Chronic), Insomnia Treatment.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Chronic Pain Section: Insomnia and Insomnia Treatment.

**Decision rationale:** The Official Disability Guidelines comment on the evaluation and management of the symptom of insomnia. These guidelines recommend correcting deficits, as nonrestorative sleep is one of the strongest predictors for pain. Definition: Difficulty in sleep initiation or maintenance, and/or early awakening. Also characterized by impairment in daily function due to sleep insufficiency. These impairments include fatigue, irritability, decreased memory, decreased concentration, and malaise. Classifications: (1) Based on symptoms: Categories of symptoms include sleep onset, sleep maintenance, non-restorative sleep. These symptoms have been found to change over time. (2) Based on duration: (a) Acute insomnia (transient insomnia): Usually the result of specific environmental or social events. Generally treated by addressing the episode directly (death of a family member, working on a different shift, travel), or prophylactically. (b) Chronic insomnia: Generally defined as lasting more than one month. This condition may be correlated with other intrinsic sleep disorders, primary

insomnia, or chronic medical conditions. Chronic insomnia is more likely to occur in the elderly, depressed patients, and medically ill populations. (3) Based on etiology: (a) Primary insomnia: No known physical or mental condition is noted as an etiology. This condition is generally consistent and responsive to treatment. (b) Secondary insomnia (comorbid insomnia): insomnia that is secondary to other medical and psychiatric illnesses, medications, or sleep disorders. Examples include chronic pain, gastroesophageal reflux disease (GERD), heart failure, end-stage renal disease, diabetes, neurologic problems, psychiatric disorders, and certain medications. Diabetic patients appear to suffer insomnia due to alterations of circadian rhythm. They may also suffer from sleep disorders related to obesity. Psychiatric disorders associated with insomnia include depression, anxiety and alcoholism. Poor or insufficient sleep is the strongest predictor for pain in adults over 50. Among factors associated with new-onset pain were: age (OR 0.97); baseline pain status (OR 1.1); anxiety (OR 1.5); physical health-related quality of life (OR 1.3); cognitive complaint (OR 1.3); & nonrestorative sleep (OR 1.9; 95% CI 1.2 - 2.8). This study points to the need to address underlying sleep problems to bring pain relief. In this case, there is insufficient documentation that the patient has undergone an assessment for the source of the insomnia. Further, the Official Disability Guidelines indicate that while sedating antidepressants (e.g., amitriptyline, trazodone, mirtazapine) have been used to treat insomnia, there is less evidence to support their use for insomnia. They may be an option in patients with coexisting depression. In this case, there is insufficient evidence that Trazodone is being used to treat coexisting depression. Finally, given the duration of use of Trazodone, there is insufficient documentation that its use is associated with improved outcomes; including reduction of episodes of insomnia and functional improvements. For these reasons, Trazodone is considered not medically necessary.