

<b>Case Number:</b>	CM15-0068738		
<b>Date Assigned:</b>	04/16/2015	<b>Date of Injury:</b>	09/25/2009
<b>Decision Date:</b>	06/16/2015	<b>UR Denial Date:</b>	03/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/10/2015

### 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 44 year old female who sustained an industrial injury on September 25, 2009. She has reported injury to the left foot and left ankle and has been diagnosed with chronic ankle strain with peroneal sensory involvement associated with plantar fasciitis, mild nonspecific discomfort along the right foot as a compensatory issue, internal derangement on the left knee, and knee pain. Treatment has included medications and bracing. Examination noted tenderness along the anterior and posterior talofibular ligament and was noted with anterior instability. There was Tinel along the sensory branch of the peroneal nerve. Mild tenderness on Achilles tendon area was noted. There was tenderness along the plantar fascia of the right foot. MRI dated February 2014 of the left knee revealed a tear of the lateral meniscus and inflammation. The treatment request included Protonix, tramadol, and trazodone.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Protonix 20mg/tab; #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Nsaids.

**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 (PPIs) such as Protonix. In general, PPIs are used to lower the risk of a significant gastrointestinal event, e.g. an ulcer or a gastrointestinal bleed, for a patient taking a NSAID. The use of a PPI is based on whether a patient is deemed to be at risk for a significant gastrointestinal event. These risks are described 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). 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 mg 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 naproxen plus low-dose aspirin plus a PPI. In this case, the records do not provide any evidence that this patient is at risk for a significant gastrointestinal event. Given the absence of documented risk, the use of a PPI such as Protonix is not medically necessary.

**Trazodone 50mg/tab; #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines antidepressants for chronic pain Page(s): 13-14. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for Pain Page(s): 13-16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Chronic Pain Section: Insomnia Treatment.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines comment on the use of the antidepressants including trazodone. There are two targets in the use of trazodone; as an antidepressant and as a medication to address insomnia. The Official Disability Guidelines comment on the use of trazodone for the treatment of insomnia. These guidelines state the following: Sedating antidepressants (e.g., amitriptyline, trazodone, mirtazapine) have also been used to treat insomnia; however, there is less evidence to support their use for insomnia, but they may be an option in patients with coexisting depression. Trazodone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation. Regarding the use of trazodone as an antidepressant to address chronic pain, the MTUS guidelines state the following:

Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. Additional side effects are listed below for each specific drug. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. In this case, it is clear that the patient has diagnosed depression; however, it is unclear as to the provider's specific intent in the use of trazodone. Given that the patient is undergoing treatment with other types of antidepressants, it appears that trazodone is being used for the treatment of insomnia; with the additional benefit of being an antidepressant. This is common practice in the community. However, there is insufficient evidence that there has been ongoing monitoring of relevant outcome measurements to determine the impact of this medication. As indicated in the above cited guidelines, these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. For this reason, trazodone is not medically necessary treatment.

**Tramadol ER 150mg/tab; #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78, 80.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids, including Tramadol. These guidelines have established criteria of the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an 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. There should be evidence of documentation of the "4 A's for Ongoing Monitoring". These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be 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 that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of

reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 A's for Ongoing Monitoring". The treatment course of opioids in this patient has extended well beyond the time frame required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Further, it should be noted that in this patient's medication list, the combination of Tramadol with some of the antidepressants prescribed, increases the risk for serotonin syndrome. Documentation that the patient has been counseled on the risk of this adverse event is not present in the medical records. For these reasons treatment with Tramadol is not medically necessary.