

<b>Case Number:</b>	CM15-0015321		
<b>Date Assigned:</b>	02/03/2015	<b>Date of Injury:</b>	01/05/2014
<b>Decision Date:</b>	03/25/2015	<b>UR Denial Date:</b>	12/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/27/2015

### 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 57 year old male, who sustained an industrial injury on 1/5/2014. The diagnoses have included lumbago, lumbar radiculitis and lumbar degenerative disc disease. Treatment to date has included epidural steroid injection (ESI), physical therapy, medications and acupuncture. Magnetic resonance imaging (MRI) of the lumbar spine dated 2/6/2014 revealed scattered hemangiomas and disc abnormalities. According to the Primary Treating Physician's Progress Report dated 11/19/2014, the injured worker complained of constant pain in the low back that was aggravated by bending, lifting, twisting, pushing, pulling, prolonged sitting, prolonged standing and walking multiple blocks. The pain was characterized as sharp. There was radiation of pain into the lower extremities. The pain was rated 8/10. Inspection of the lumbar spine revealed restricted range of motion. The injured worker was pending authorization for lumbar surgery. There was tingling and numbness in the lateral thigh, anterolateral and posterior leg as well as foot, L5 and S1 dermatomal patterns. Authorization was requested for medications. On 12/30/2014, Utilization Review (UR) non-certified requests for Fenoprofen Calcium (Nalfon) 400mg #120, Omeprazole delayed-release capsules 20mg #120, Cyclobenzaprine Hydrochloride tab 7.5mg #120, Tramadol ER 150mg #90 and Eszopiclone (Lunesta) tablets 1mg #30. The Medical Treatment Utilization Schedule (MTUS), American College of Occupational and Environmental Medicine (ACOEM) Guidelines and Official Disability Guidelines (ODG) were cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fenoprofen Calcium (Nalfon) 400mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non steroidal anti inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-68.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs, such as Fenoprofen, as a treatment modality. These guidelines state the following: Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. Back Pain - Chronic low back pain: 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. In this case the available information from the records indicates that Fenoprofen is being used as a long-term treatment modality for this patient's symptoms. For this reason, given the above cited recommendations, the use of Fenoprofen is not medically necessary.

**Omeprazole Delayed -Release Capsules 20mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non steroidal anti inflammatory drugs).

**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 a treatment modality. PPIs are recommended under the following conditions: 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 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, there is insufficient evidence provided in support of the use of a PPI. The records indicate that the patient does not have any of the factors that would place him at risk for a gastrointestinal event to include a gastrointestinal bleed or ulcer. For this reason, per the above cited guidelines, Omeprazole is not considered as a medically necessary treatment.

**Cyclobenzaprine Hydrochloride Tab 7.5mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-66.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of muscle relaxants, such as cyclobenzaprine, as a treatment modality. These guidelines state the following:Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. 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. In this case, the records indicate that Cyclobenzaprine is being used as a long-term treatment modality for this patient's symptoms. For this reason, Cyclobenzaprine is not considered as a medically necessary treatment.

**Tramadol ER 150mg #90:** 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, such as Tramadol ER. These guidelines have established criteria on 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 back 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 timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Tramadol is not considered as medically necessary.

**Eszopiclone (Lunesta) Tablets 1mg (Civ) #30: 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 Procedure Summary and Med Lett Drugs Ther.

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

**Decision rationale:** The Official Disability Guidelines comment on the use of Lunesta (eszopiclone) for the treatment of insomnia. These guidelines state the following: Lunesta is not recommended for long-term use, but recommended for short-term use. In this case the records indicate that Lunesta is being used as a long-term treatment modality for this patient's sleep disorder. Per the above cited guidelines, this is not recommended. For this reason, Lunesta is not considered as a medically necessary treatment.