

<b>Case Number:</b>	CM15-0163086		
<b>Date Assigned:</b>	09/14/2015	<b>Date of Injury:</b>	08/25/1982
<b>Decision Date:</b>	10/14/2015	<b>UR Denial Date:</b>	07/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/19/2015

### 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: Tennessee, Florida, Ohio  
 Certification(s)/Specialty: Surgery, Surgical Critical Care

### 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 70-year-old male who sustained an industrial injury on August 25, 1982. A pain management follow up dated June 19, 2015 reported subjective complaint of continued low back pain and bilateral hip and leg pain. "He is stable on his current medication regimen". There is note of unsuccessful request for injection therapy. The impression noted the worker with lumbar spondylosis and lumbar sciatica. Pain management follow up dated February 27, 2015 reported the worker denying any new pains, changes in pain, or new neurologic issue. He further states he is not having any issue with his current medication regimen. "After medicating with Morphine Sulphate IR and Morphine Sulphate ER his pain is decreased to a 5 in intensity." He is to comply with primary care physician regarding depression. The plan of care is with recommendation to continue with current medications to include: Morphine Sulphate ER and IR; Opioid agreement signed. Past primary visit dated November 14, 2014 report current medication regimen consisting of: Flexeril, Lunesta, Morphine Sulphate IR, ER, and Nexium. Medication regimen at follow up dated July 11, 2014 reported medication regimen consisting of: Opana and Morphine Sulphate for break through pains. The plan of care noted discontinuing Opana and going back to Morphine Sulphate Contin.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cilostazol 100mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.nlm.nih.gov](http://www.nlm.nih.gov).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pletal Indications for Use, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2007/020863s021lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020863s021lbl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address the topic of this medication. Therefore, outside sources were sought. Per its FDA indications for use, Pletal is an anti-platelet agent that is indicated for claudication, s/p stents, and secondary prevention of TIA and non-cardioembolic stroke. This patient has a history of industrial exposure to tetrachloride with secondary pulmonary symptomatology. Pletal is not a treatment for the industrial-caused diagnoses that the patient is suffering from. Furthermore, the patient's most recent clinic notes fail to address the patient's lower extremity claudicative symptoms for which she takes this medication. Therefore, based on the submitted medical documentation, the request for Pletal is not medically necessary.

#### **Doxazosin Mesylate 4mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.nlm.nih.gov](http://www.nlm.nih.gov).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Doxazosin FDA Indications for Use, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/019668s021lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019668s021lbl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address the topic of this medication. Therefore, outside sources were sought. Per its FDA indications for use, Doxazosin is an alpha-blocker that is indicated for the treatment of both the urinary outflow obstruction and obstructive and irritative symptoms associated with benign prostatic hypertrophy: obstructive symptoms (hesitation, intermittency, dribbling, weak urinary stream, incomplete emptying of the bladder) and irritative symptoms (nocturia, daytime frequency, urgency, burning). The medical documentation supports that this patient has a history of chronic back pain and hypertension. However, the patient's most recent clinic records fail to document the patient is voiding habits or any obstructive/irritative symptomatology associated with BPH. Clinical documentation and follow-up is necessary to serially follow the patient's prescribed treatment. Therefore, based on the submitted medical documentation, the request for Doxazosin is not medically necessary.

#### **Enalapril Maleate 2.5mg: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [Mdconsult.com](http://Mdconsult.com).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Indications for Use: [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2001/18-998s058\\_Vasotec.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/18-998s058_Vasotec.cfm).

**Decision rationale:** There is sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The clinical records submitted do support the fact that this patient has coronary artery disease and hypertension. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of enalapril prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for enalapril use, the medication is indicated for hypertension, acute Myocardial Infarction and congestive heart failure. This patient's medical records support that he has refractory hypertension, which is not associated with congestive heart failure. This is an appropriate and first line indication for use of an ACE inhibitor. Use of enalapril for treatment of this patient's hypertension is clinically appropriate. The patient's recent clinic vitals support that his blood pressure is borderline controlled. Continuation of the medication is appropriate since ACE inhibitors have been demonstrated to have an overall mortality benefit due to their cardio protective effects. Therefore, based on the submitted medical documentation, the request for enalapril prescription is medically necessary.

**Provigil 200mg #30 x 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Provigil.

**Decision rationale:** The California MTUS guidelines and the ACOEM Guidelines do not this topic. Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder. Per the Occupational Disability Guidelines, "Patients should have a complete evaluation with a diagnosis made in accordance with the International Classification of Sleep Disorders or DSM diagnostic classification prior to prescription". It is: "Not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing." The medical documentation does not reflect that this patient has had a complete evaluation with a diagnosis made in accordance with the DSM or International Classification of Sleep Disorders. The patient has no documentation of daytime drowsiness or narcolepsy on his recent clinical encounter. Therefore, based on the submitted medical documentation, the request for Provigil is not medically necessary.

**Morphine sulfate 15mg #90:** 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): Opioids, dosing.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The clinical records submitted do not support the fact that this patient has a dose, which does not exceed 120 mg oral morphine equivalents per day. In accordance with California MTUS guidelines, narcotics for chronic pain management should be continued if "(a) If the patient has returned to work, (b) If the patient has improved functioning and pain." MTUS guidelines also recommends that dosing "not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine

equivalent doses of the different opioids must be added together to determine the cumulative dose." The dose of opioids prescribed this patient far exceeds that of 120mg oral morphine equivalents per day. Therefore, based on the submitted medical documentation, the request for Morphine Sulfate 15mg #90 is not-medically necessary.

**Morphine sulfate ER 15mg #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): Opioids, dosing.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The clinical records submitted do not support the fact that this patient has a dose, which does not exceed 120 mg oral morphine equivalents per day. In accordance with California MTUS guidelines, narcotics for chronic pain management should be continued if "(a) If the patient has returned to work, (b) If the patient has improved functioning and pain." MTUS guidelines also recommends that dosing "not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose." The dose of opioids prescribed this patient far exceeds that of 120mg oral morphine equivalents per day. Therefore, based on the submitted medical documentation, the request for Morphine Sulfate ER 15mg #60 is not-medically necessary.

**Celebrex 200mg #30 x 3 refills:** 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), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, hypertension and renal function, NSAIDs, specific drug list & adverse effects.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of treatment of this medication for this patient. The California MTUS guidelines address the topic of NSAID prescriptions by stating, "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." The MTUS guidelines do not recommend routine use of NSAIDs due to the potential for adverse side effects (GI bleeding, ulcers, renal failure, etc). The medical records do not support that the patient has a contraindication to other non-opioid analgesics. Therefore, medical necessity for Celebrex prescription has not been established.

**QVar 2 puffs:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.nlm.nih.gov](http://www.nlm.nih.gov).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation QVAR FDA Indications for Use, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/020911s0221bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020911s0221bl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address the topic of this medication. Therefore, outside sources were sought. Per its FDA indications for use, QVAR is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. This patient has a history of industrial exposure to tetrachloride with secondary pulmonary symptomatology. However, the patient's most pulmonary function tests revealed normal lung function without obstructive or restrictive defects. Lung function was also not improved by bronchodilator therapy. Asthma is a restrictive lung disease. This patient has not been demonstrated to have either asthma or any restriction on pulmonary function testing. Therefore, based on the submitted medical documentation, the request for QVAR is not medically necessary.

**Flexeril (Cyclobenzaprine HCL) 10mg #90: 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:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. In accordance with the California MTUS guidelines, Cyclobenzaprine is a muscle relaxant and muscle relaxants are not recommended for the treatment of chronic pain. From the MTUS guidelines: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic back pain". Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. This patient has been diagnosed with chronic pain of the hip, spine and leg. Per MTUS, the use of a muscle relaxant is not indicated. Therefore, based on the submitted medical documentation, the request for Cyclobenzaprine is not-medically necessary.

**Lunesta 3mg #30 x 3 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress, Zolpidem.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of this medication. Per the Official Disability Guidelines (ODG), "Lunesta is not recommended for long-term use." The clinical records submitted do support the fact that this patient has a chronic pain of the hip, spine and leg with a history of insomnia. However, the ODG guidelines do not support the long-term use of this medication for

that indication. Therefore, based on the submitted medical documentation, the request for Lunesta is not-medically necessary.

**Nexium 20mg #30 x 3 refills:** 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:** There is not sufficient clinical information provided to justify the medical necessity of a Nexium prescription for this patient. Nexium is the name brand equivalent of generic, esomeprazole. The clinical records submitted do not support the fact that this patient has refractory GERD resistant to H2 blocker therapy or an active h. pylori infection. The California MTUS guidelines address the topic of proton pump prescription. In accordance with California MTUS guidelines, PPI's (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDS and if the patient has gastrointestinal risk factors. This patient is on NSAIDS; however, he does not have any additionally documented GI risk factors. Per the Federal Drug Administration's (FDA) prescribing guidelines for Nexium use, chronic use of a proton pump inhibitor is not recommended due to the risk of developing atrophic gastritis. Short-term GERD symptoms may be controlled effectively with an H2 blocker unless a specific indication for a proton pump inhibitor exists. Therefore, based on the submitted medical documentation, the request for Nexium prescription is not medically necessary.

**Beconase AQ 0.042 mg/inh spray:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape.com.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Beconase FDA Indications for Use, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2001/19389s23lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2001/19389s23lbl.pdf).

**Decision rationale:** Per its FDA indications for use, Beconase Inhalation Aerosol is indicated for the relief of the symptoms of seasonal or perennial rhinitis in those cases poorly responsive to conventional treatment. This patient has a history of industrial exposure to tetrachloride with secondary pulmonary symptomatology. However, the patient's most pulmonary function tests revealed normal lung function without obstructive or restrictive defects. Lung function was also not improved by bronchodilator therapy. The most recent medical encounter for this patient does not document any evidence of rhinitis. Furthermore, there is not documentation that the patient has failed other conventional treatments for allergic rhinitis. Therefore, based on the submitted medical documentation, the request for Beconase is not medically necessary.

**Potassium chloride SR 20mcg SUS:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA), Potassium Chloride Indications Use and Prescribing Information, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM270390.pdf>.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a Potassium Chloride prescription for this patient. The clinical records submitted do not support the fact that this patient has hypokalemia. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Potassium Chloride prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Potassium Chloride use, the medication is only indicated for treatment of hypokalemia. The patient's medical records do not support that they have hypokalemia. Recent lab testing for potassium wasting has not been clinically documented. Without confirmation of hypokalemia, a potassium prescription is not appropriate. Therefore, based on the submitted medical documentation, the request for potassium chloride prescription is not medically necessary.

**ProAir HFA CFC free 90mcg/AERS:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pulmonary procedure.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ProAir FDA Indications for Use, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2008/021457s013lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021457s013lbl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address the topic of this medication. Therefore, outside sources were sought. This patient has a history of industrial exposure to tetrachloride with secondary pulmonary symptomatology. However, the patient's most pulmonary function tests revealed normal lung function without obstructive or restrictive defects. Lung function was also not improved by bronchodilator therapy. Per its FDA label, Proair is generically known as albuterol. Albuterol is a bronchodilator. Since an objective improvement in pulmonary function was not demonstrated on testing, further prescription of this medication is not indicated. Therefore, based on the submitted medical documentation, the request for ProAir HFA CFC free 90mcg is not medically necessary.

**Baclofen 10mg #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a Baclofen prescription for this patient. The clinical records submitted do support the fact that this patient has chronic lower back pain. However, the records indicate that this

patient has been on the medication for longer than 2 weeks with no recent documentation of muscle spasms. The California MTUS guidelines address the topic of muscle relaxant prescription. In accordance with the California MTUS guidelines, Baclofen is a muscle relaxant and muscle relaxants are not recommended for the treatment of chronic pain. From the MTUS guidelines: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence." The documentation reflects that Baclofen is being prescribed for this patient's chronic pain. The presence of muscle spasms is not documented in this patient's recent clinical records. Documentation of the continued need for Baclofen prescription is not supported. Therefore, based on the submitted medical documentation, the request for baclofen prescription is not-medically necessary.