

<b>Case Number:</b>	CM15-0171479		
<b>Date Assigned:</b>	09/17/2015	<b>Date of Injury:</b>	08/04/2005
<b>Decision Date:</b>	11/10/2015	<b>UR Denial Date:</b>	08/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/31/2015

### 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: Emergency Medicine

### 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 58 year old female who sustained an industrial injury on 8-4-2005. A review of medical records indicated the injured worker is being treated for failed cervical fusion surgeries at C5-6 fusion on 10-16-2006 as well as C4-5 fusion around 9-26-2008 with residual severe significant chronic pain, as well as chronic bilateral cervical radiculitis more prominent on the right than the left, and right wrist and hand tendonitis and carpal tunnel syndrome. Medical records dated 7-10-2015 noted cervical spine pain rated a 4-5- out 10, right wrist and hand a 7-8 out 10. Pain does decrease with medication by 50% and allows her to continue with her activities of daily living. Medical records dated 5-8-2015 noted cervical pain a 4 out of 10 and right wrist and hand pain was an 8 out of 10. Physical examination dated 7-10-2015 noted palpation of the paracervical muscles showed moderate muscle spasm or tightness greater on the right than the left extending into the interscapular region. Range of motion was reduced. There was mild tenderness of the volar and dorsal wrist. There was decreased range of motion. Treatment has included medication since at least 2-4-2015. The Utilization review form dated 8-7-2015 included Voltaren gel, Vivovo, Phenergan, Omeprazole, Linzess, Lidocaine, Flexeril, and housework help.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flexeril 10mg q 8 hours as needed for muscle spasms: 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 request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate qualifying evidence and prolonged duration of use, the request is not medically necessary.

**Linzess 290mcg q.d.6.: 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) Pain (Chronic)/Opioid-induced constipation treatment.

**Decision rationale:** The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not

from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for noncancerous-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic noncancerous-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for noncancerous pain. (FDA, 2014) As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not indicated. The patient is currently on a medication in the opioid class with the resultant side effect of constipation. There is a lack of documentation of first line therapy failure. As such, the request is not medically necessary.

**Omeprazole 20mg every day:** 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:** The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet the above stated criteria, the request for use is not medically necessary.

**Lidocaine 5% patch, up to 2 per day (unknown quantity):** 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): Topical Analgesics.

**Decision rationale:** The request is for the use of a Lidoderm patch to aid in pain relief. The MTUS guidelines state that its use is indicated for post herpetic neuralgia after an initial trial of an anti-epileptic medication. Further research is needed to recommend use for chronic neuropathic disorders besides post-herpetic neuralgia. In this case, the patient does not have a diagnosis documented which would justify the use of Lidoderm patches. As such, the request is not medically necessary.

**Phenergan suppository 25mg, up to 2 per day:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Antiemetics (for opioid nausea).

**Decision rationale:** The request is for the use of phenergan. This is a medication in the phenothiazine class and it is usually used for nausea in certain circumstances. The MTUS guidelines are silent regarding this issue but the ODG state the following: Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Promethazine (Phenergan): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus). In this case, as indicated above, the patient does not qualify for the use of this medication. It is not indicated for use in patients who develop nausea or vomiting secondary to chronic opioid use. As such, the request is not medically necessary.

**Vimovo 500/20mg, 1-2 per day (unknown quantity):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor and NSAID combined. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

**Voltaren gel 1% 100grams:** 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): Topical Analgesics.

**Decision rationale:** The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.

**Continue to authorize housework help:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** The request is for home health services to aid in care. The MTUS and ACOEM guidelines are silent regarding this topic. The ODG guidelines state the following: "Recommended on a short-term basis following major surgical procedures or in-patient hospitalization, to prevent hospitalization, or to provide longer-term in-home medical care and domestic care services for those whose condition is such that they would otherwise require inpatient care. Home health care is the provision of medical and other health care services to the injured or ill person in their place of residence. Home health services include services deemed to be medically necessary for patients who are confined to the home (homebound) and who require: (1) Skilled care by a licensed medical professional for tasks including, but not limited to, administration of intravenous drugs, dressing changes, occupational therapy, physical therapy, and speech-language pathology services; with or without additionally requiring (2) Personal care services for tasks and assistance with activities of daily living that do not require skills of a medical professional, such as bowel and bladder care, feeding, bathing, dressing and transfer and assistance with administration of oral medications; and/or (3) Domestic care services such as shopping, cleaning, and laundry that the individual is no longer capable of performing due to the illness or injury that may also be medically necessary in addition to skilled and/or personal care services. Services described under (2) and (3) should be covered only when (1) is justified. An employer or their insurer shall not be liable for household tasks the injured worker's spouse or other member of the injured worker's household performed prior to the injury free of charge. (CMS, 2015) Domestic and personal care services do not require specialized training and do not need to be performed by a medical professional. (ACMQ, 2005) (Ellenbecker, 2008) See also Skilled nursing facility (SNF) care." As indicated above, home health is indicated on a short-term basis following major surgical procedures or hospitalization. It is medically necessary for those that are homebound and require skilled or personal care services. In this case, the patient does not meet the criteria necessary. As such, the request is not medically necessary.