

<b>Case Number:</b>	CM15-0065010		
<b>Date Assigned:</b>	04/10/2015	<b>Date of Injury:</b>	08/16/2003
<b>Decision Date:</b>	06/05/2015	<b>UR Denial Date:</b>	03/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/03/2015

### 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: New York  
 Certification(s)/Specialty: Anesthesiology

### 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 50 year old male who sustained an industrial injury on 08/16/2003. Current diagnoses include post laminectomy syndrome and inflammatory spondylopathy. Previous treatments included medication management, and spine surgery. Report dated 02/02/2015 noted that the injured worker presented for follow-up and refill of prescriptions. Pain level was not included. Physical examination was positive for abnormal findings. The treatment plan included prescriptions for Protonix and promethazine, and follow up in four weeks. Disputed treatments include promethazine, Protonix, Gralise, sublingual buprenorphine, and Lidocaine 5% ointment.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**75 Tabs of Promethazine 25 MG:** Upheld

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

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

**Decision rationale:** Promethazine (Phenergan) is an anti-emetic. However, it is not recommended for nausea and vomiting secondary to chronic opioid use. Studies of opiate 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. In this case, there is no documentation of opioid related nausea and vomiting. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

**60 Tabs of Protonix 20 MG: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PPIs Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to CA MTUS (2009), proton pump inhibitors, such as Protonix (Pantoprazole), are recommended for patients at risk for gastrointestinal events or taking NSAIDs with documented GI distress symptoms. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation of any reported GI complaints. Based on the available information provided for review, the medical necessity for Protonix has not been established. The requested medication is not medically necessary.

**5 Tabs of Gralise 600 MG (Sample Pack) with 4 Refills: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 17-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neurontin.

**Decision rationale:** Gabapentin (Gralise) is an anti-epilepsy drug, which has been shown to be effective for the treatment of painful diabetic neuropathy and post-herpetic neuralgia, and has been considered as a first-line treatment for neuropathic pain. Gralise is also FDA approved as a second-line option for restless leg syndrome, however, there is no documentation of this for this patient. In this case, the patient has chronic low back pain but there is no evidence of neuropathic pain. Gralise is considered a first-line treatment for neuropathic pain. Medical necessity for this requested medication has not been established. The requested medication is not medically necessary.

**240 Sublinguals of Buprenorphine HCL 2 MG: Upheld**

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

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

**Decision rationale:** Butrans (Buprenorphine) is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It blocks effects of subsequently administered opioid agonists. Butrans is recommended as an option for the treatment of chronic pain in selected patients (not first-line for all patients) including, with a hyperalgesic component to pain, patients with centrally mediated pain, and patients with neuropathic pain. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's pain relief effectiveness, functional status, or response to ongoing opioid analgesic therapy. Medical necessity of the requested medication has not been established. Of note, discontinuation of an opioid analgesic should include a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

**60 Tubes of Lidocaine 5 Percent Ointment:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, there is no documentation of intolerance to other previous oral medications. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) is FDA approved for neuropathic pain, and used off-label for diabetic neuropathy. No other Lidocaine topical creams or lotions are indicated for neuropathic or non-neuropathic pain. Medical necessity for the topical analgesic cream has not been established. The requested medication is not medically necessary.