

<b>Case Number:</b>	CM15-0103860		
<b>Date Assigned:</b>	06/08/2015	<b>Date of Injury:</b>	02/03/2004
<b>Decision Date:</b>	07/08/2015	<b>UR Denial Date:</b>	05/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/29/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 52 year old female who sustained an industrial injury on 02/03/2004. Mechanism of injury was not documented. She has pain in her cervical spine. Diagnoses include long term use of medications, cervical disc displacement without myelopathy, lumbar disc displacement without myelopathy, and Multiple Sclerosis. Treatment to date has included diagnostic studies, and medications. Her medications include Protonix, Topamax, and Ketamine 5% cream, Norflex ER, Venlafaxine Hcl ER, and Morphine Sulfate ER. A physician progress note dated 05/13/2015 documents the injured worker the injured worker has severe neck pain radiating into the trapezius muscles down both arms, predominantly on the left. She complains of weakness in her left hand and difficulty holding pots and pans and putting away dishes. She also suffers from back, leg and knee pain. There is tenderness to palpation on the trapezius and cervical paraspinal. Range of motion is fairly well preserved. The treatment plan is for a cervical Magnetic Resonance Imaging, Topamax, Venlafaxine Hcl ER, and Morphine Sulfate ER. Treatment requested is for Ketamine 5% Cream 60gm Qty 1, Orphenadrine-Norflex ER 100mg Qty 900, and Pantoprazole-Protonix 20mg Qty 60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

### **Pantoprazole-Protonix 20mg qty 60: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** MTUS states, "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)." And "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)." ODG states, "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" The medical documents provided establish the patient has experienced GI discomfort and has a history of stomach ulcer. In addition, the treating physician has provided documentation of a failed trial of omeprazole. As such, the request for Pantoprazole-Protonix 20mg qty 60 is medically necessary.

### **Ketamine 5% Cream 60gm qty 1: Overturned**

**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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed". The medical documents indicate failure of Neurontin and Lyrica. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical Ketamine, "Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary

and secondary treatment has been exhausted." Medical records indicate that the patient has failed treatments including: PT, acupuncture, TENs trial, Chiropractic care, surgeries, exercises, injections, modified duty, medications; Capsaicin cream, Gabapentin cream, Lidocaine cream, Norco, Zanaflex, Flexeril, Buprenorphine, Lodine, Anaprox, Fentanyl patch, Baclofen, Soma and Duragesic patch. The patient has GI side effects due to oral medications. The patient reports pain level is reduced from 7-8/10 to 5/10 on VAS score with the use of Ketamine. Treating physician documents the medication is only used as needed and is tolerated well without side effects. As such, the request for Ketamine 5% Cream 60gm qty 1 is medically necessary.

**Orphenadrine-Norflex ER 100mg qty 900:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-65.

**Decision rationale:** Norflex is classified as a muscle relaxant. MTUS states, "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." ODG recommends limited muscle relaxant usage to 2 weeks in duration. Additionally, MTUS states "Orphenadrine (Norflex, Banflex, Antiflex, Mio-Rel, Orphenate, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959. Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. (Shariatmadari, 1975) Dosing: 100 mg twice a day; combination products are given three to four times a day. (See, 2008)" MTUS guidelines recommend against the long term use of muscle relaxants. The patient has been on this muscle relaxant since at least 9/2014. Guidelines recommend against long term muscle relaxant usage. The treating physician has not detailed how NSAIDs is inferior to norflex, per MTUS guidelines. As written, the prescription is for 30 days of medication, which is still in excess of the recommended 2 week limit. The medical documents do not indicate extenuating circumstances to allow for exceptions to the guidelines. As such, the request for Orphenadrine-Norflex ER 100mg qty 90 is not medically necessary.