

<b>Case Number:</b>	CM15-0130094		
<b>Date Assigned:</b>	07/16/2015	<b>Date of Injury:</b>	03/27/2007
<b>Decision Date:</b>	09/18/2015	<b>UR Denial Date:</b>	06/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/06/2015

### 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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:

This 50-year-old woman sustained an industrial injury on 3/27/2007. The mechanism of injury is not detailed. Diagnoses include lumbar spinal stenosis, cervical disc displacement, lumbar disc degeneration, lumbar disc displacement without myelopathy, and disorders of the sacrum. Treatment has included oral medications, functional restoration program, sacroiliac joint injection, transforaminal lumbar epidural steroid injection, and lumbar radiofrequency ablation injection. Physician notes dated 5/26/2015 show complaints of constant low back pain with radiation to the left leg. Recommendations include three topical medications, Protonix, Venlafaxine, Tramadol/Acetaminophen, and follow up in four weeks.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Diclofenac Sodium 1.5% 60gm #1:** 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain; compounds.

**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 do not indicate failure of antidepressants or anticonvulsants. 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 NSAIDs, "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. Neuropathic pain: Not recommended as there is no evidence to support use." The employee has low back pain, which the guidelines recommend against treating with topical diclofenac. Therefore, the request is not medically necessary.

**Ketamine 5% Cream 60gm #1:** 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain; Compounds.

**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 do not indicate failure of antidepressants or anticonvulsants. 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 do not indicate that all primary and secondary treatment options have been exhausted. Therefore, the request is not medically necessary.

**Pantoprazole-Protonix 20mg #60:** Upheld

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

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

**Decision rationale:** Protonix is the brand name version of Pantoprazole, which is a proton pump inhibitor. 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 patient does not meet the age recommendations for increased GI risk. The medical documents provided establish the patient has experienced GI discomfort, but is nonspecific and does not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally per guidelines, Pantoprazole is considered second line therapy and the treating physician has not provided detailed documentation of a failed trial of omeprazole and/or lansoprazole. As such, the request is not medically necessary.

**Doxepin 3.3% Cream 60gm #1:** Upheld

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

**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; compounds.

**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 do not indicate failure of antidepressants or anticonvulsants. 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." There is no evidence of failure of first line agents. Therefore, the request is not medically necessary.

**Tramadol/Apap 37.5/325mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids; Tramadol Page(s): 74-123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

**Decision rationale:** Ultram is the brand name version of tramadol, which is classified as central acting synthetic opioids. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/acetaminophen." The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of tramadol prior to the initiation of this medication. The original utilization review recommended weaning and modified the request, which is appropriate. As such, the request is not medically necessary.