

<b>Case Number:</b>	CM15-0205978		
<b>Date Assigned:</b>	10/22/2015	<b>Date of Injury:</b>	07/13/2014
<b>Decision Date:</b>	12/24/2015	<b>UR Denial Date:</b>	09/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/20/2015

### 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:

This is a 43 year old male with a date of injury of July 13, 2014. A review of the medical records indicates that the injured worker is undergoing treatment for lumbar herniated nucleus pulposus with radiculopathy of the right lower extremity, anxiety and insomnia. Medical records dated August 18, 2015 indicate that the injured worker complained of moderate to sharp pain in the lower back rated at a level of 5 to 6 out of 10 that radiates to the buttocks and right leg. The medial record also notes that the injured worker had activity limitations due to pain including walking, lifting, sitting, standing, sleeping, social activities, traveling in a car, bathing and showering, and doing jobs around the house. Per the treating physician, the employee has not returned to work. The physical exam reveals slight stiffness of stance and gait, tenderness to palpation of the lumbar spine with trigger points and spasm, decreased range of motion of the lumbar spine, positive Lasegue's Cram's and sciatic notch signs, and positive straight leg raise bilaterally. Treatment has included physical therapy, magnetic resonance imaging of the lumbar spine (November 18, 2014) that showed degenerative disc disease at L4-5, anterior spondylosis, and a central annular tear, and medications (over the counter medications not specified). The utilization review (September 29, 2015) non-certified a request for topical Ketoprofen cream, topical Gabapentin cream, and topical Tramadol cream, and partially certified a request for Tramadol 150mg #5 (original request for #60), Prilosec 20mg #30 (original request for #90), and Flexeril 7.5mg #20 (original request for #60).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen cream, quantity: 1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**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. Ketoprofen is not currently FDA approved for a topical application, and has an extremely high incidence of photo-contact dermatitis. Medical necessity for the requested topical analgesic cream has not been established. The request for the compounded topical analgesic cream is not medically necessary.

**Gabapentin cream, quantity: 1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**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. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. Medical necessity for the requested topical analgesic cream has not been established. The request for the topical analgesic cream is not medically necessary.

**Tramadol cream, quantity: 1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**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. Tramadol is not FDA approved for a topical application. There is no peer-reviewed literature to support its use. Medical necessity for the requested topical analgesic cream has not been established. The request for the topical analgesic agent is not medically necessary.

**Tramadol 150mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, pain treatment agreement.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids.

**Decision rationale:** According to the California MTUS, Tramadol (Ultram) is a synthetic opioid which affects the central nervous system and is indicated for the treatment of moderate to severe pain. Per CA MTUS Guidelines, certain criteria need to be followed, including an ongoing review and documentation of pain relief and functional status, appropriate medication use, and side effects. Pain assessment should include current pain: last reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid, and the duration of pain relief. According to the medical records, there has been no documentation of the medication's analgesic effectiveness and no clear documentation that the patient has responded to ongoing opioid therapy. Medical necessity of the requested medication has not been established. Of note, discontinuation of an opioid analgesic requires a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Prilosec 20mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to CA MTUS (2009), proton pump inhibitors, such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. 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 Prilosec has not been established. The requested medication is not medically necessary.

**Flexeril 7.5mg #60:** Upheld

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

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

**Decision rationale:** According to the reviewed literature, Cyclobenzaprine (Flexeril) is a skeletal muscle relaxant and a central nervous system (CNS) depressant. It is closely related to the tricyclic antidepressants. It is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. In addition, this medication is not recommended to be used for longer than 2-3 weeks. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than nonsteroidal anti-inflammatory medications alone. In this case, the available records show that the patient has not shown a documented benefit or any functional improvement from prior Cyclobenzaprine use. In addition, there is no clinical indication presented for the chronic or indefinite use of this medication. Based on the currently available information, the medical necessity for this muscle relaxant medication has not been established. The requested medication is not medically necessary.