

<b>Case Number:</b>	CM15-0115923		
<b>Date Assigned:</b>	06/24/2015	<b>Date of Injury:</b>	07/13/2005
<b>Decision Date:</b>	07/29/2015	<b>UR Denial Date:</b>	05/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/16/2015

### 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 51 year old male, who sustained an industrial injury on 7/13/2005. The mechanism of injury was not noted. The injured worker was diagnosed as having lumbar radiculopathy, post-laminectomy syndrome, spasm of muscle, nonsteroidal anti-inflammatory drug induced gastritis, and opioid related constipation. Treatment to date has included diagnostics, lumbar surgeries in 2005 and 2007, unsuccessful spinal cord stimulator trial in 2009, morphine pump implant in 2010 without complications, and medications. Currently, the injured worker reported left radicular symptoms, increased tingling (left greater than right). He reported awakening at night due to back pain. Pain was rated 5/10 (6/10 previous visit). He reported being more active (vacuum car, camping, able to walk around mall). The use of muscle relaxant helped to reduce the chronic muscle spasms concentrated in the low back and around his pain pump. Physical exam noted him to walk with a limp, favoring the left leg. Bilateral tenderness and spasm of the L3-5 paraspinal muscles was noted, along with decreased range of motion. Motor strength was 5+ in the right lower extremity and 4/5 in the left. Decreased sensation along the left lateral leg and thigh was noted. Urine toxicology (9/2011) was referenced as all negative. His current medication regime was helping control his symptoms so he could take care of his spouse. He reported not getting Cymbalta approved, (possibly contributing to increased pain). Medication refills were requested, including Butrans, Prilosec, Gabapentin, Flexeril, Docuprene, Flurbiprofen cream, Lidocaine patches. The rationale for Theramine was noted as to safely and effectively manage pain and inflammation. Urine toxicology (5/19/2015) was submitted

(negative for Butrans). His work status was with permanent restrictions and he was not working. The duration of use, of the requested medications, could not be determined.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **30 Flexeril 7.5mg: 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.

**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. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than nonsteroidal anti-inflammatory medications alone. The medication has its greatest effect in the first four days of treatment. It is not recommended for the long-term treatment of chronic pain. In this case, there is no documentation of functional improvement from any previous use of this medication. Based on the currently available information, the medical necessity for this muscle relaxant medication has not been established. The requested treatment is not medically necessary.

#### **30 Lidocaine patches: 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): 56-57.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics, such as the Lidoderm 5% patch, 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, for example, NSAIDs, opioids, or antidepressants. Lidoderm is the brand name for a lidocaine patch. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants, or an AED, such as gabapentin or Lyrica). Lidoderm patches are not a first-line treatment and are only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, medical necessity of the requested item has not been established. The certification of the requested Lidoderm patches is not recommended and is not medically necessary.

## **90 Theramine:** Upheld

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

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

**Decision rationale:** According to the ODG, Theramine is an FDA regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Its mechanism of action is the production of neurotransmitters that help manage and improve the sensory response to pain and inflammation. This medication contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa. There is no medical literature that supports the use of this medication for the treatment of chronic pain. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

## **Flurbiprofen cream:** 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 anti-convulsants 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, the topical medication is Flurbiprofen cream. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). There is no documentation of intolerance to other previous oral medications. The medical necessity of the requested medication has not been established. The requested medication is not medically necessary.

## **1 Urine toxicology screen:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Screen Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Urine Drug Testing (UDT).

**Decision rationale:** According to CA MTUS (2009), a urine drug screen is recommended as an option to assess for the use or the presence of illegal drugs. According to ODG, urine drug testing (UDT) is a recommended tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. In this case, the patient had a urine drug screen performed between 2/12/2015 and 4/4/2015. The treating provider has indicated that the patient is at "low risk" of addiction/aberrant drug behavior. Yearly urine drug screening is appropriate for patients considered "low risk". There is no specific indication for a urine drug screen at this time. Medical necessity for the requested test has not been established. The requested test is not medically necessary.