

<b>Case Number:</b>	CM15-0161091		
<b>Date Assigned:</b>	08/27/2015	<b>Date of Injury:</b>	09/29/2012
<b>Decision Date:</b>	10/21/2015	<b>UR Denial Date:</b>	07/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/17/2015

### 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, California  
 Certification(s)/Specialty: Emergency 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 38 year old male, who sustained an industrial injury on 9-29-2012. The current diagnoses are status post blunt head injury with post traumatic cephalgia, facial contusion, dental trauma, cervical sprain-strain, cervical spine disc protrusion, status post lumbar spine surgery, left elbow lateral epicondylitis, status post left wrist surgery, history of left wrist radius fracture with triangular fibrocartilage complex tear, history of left wrist ulnar styloid fracture with non-union, major depressive disorder, anxiety disorder, and insomnia. According to the progress report dated 6-9-2015, the injured worker complains of pain in the neck, back, left elbow, and left wrist. In addition, he reports headaches, dental problems, depression, anxiety, and sleeping problems. On a subjective pain scale, he rates his headaches 3-4 out of 4, neck and upper-mid back pain 5-6 out of 10, low back 5-8 out of 10, left elbow 4-6 out of 10, and left wrist 4-5 out of 10. The physical examination of the head and face reveals tenderness to palpation over the frontal area. There was ptosis noted in the left eye. Examination of the cervical spine reveals tenderness to palpation over the bilateral occipital muscles, bilateral suboccipital muscles, bilateral trapezius muscles, and bilateral scapulae muscles, palpable spasm over the bilateral paraspinal muscles, bilateral occipital muscles, bilateral suboccipital muscles, bilateral trapezius muscles, bilateral levator scapulae muscles, restricted range of motion, and positive cervical compression. Examination of the thoracic spine reveals tenderness to palpation over the paraspinal muscles, bilateral upper thoracic region, bilateral mid thoracic region, and bilateral lower thoracic region. There was muscle spasm over the bilateral upper thoracic region, bilateral mid thoracic region, and bilateral lower thoracic region. Restricted range of motion was noted. Examination of the lumbar spine reveals tenderness to palpation over the bilateral paraspinal muscles with spasm, restricted range of motion, and positive straight leg raising test

bilaterally. Examination of the upper extremities reveals tenderness to palpation over the anterior, posterior, lateral, and medial aspects on the left. The current medications are not specified. There is documentation of ongoing treatment with Tramadol since at least 1-2-2015. Treatment to date has included medication management, physical therapy, MRI studies, and surgical intervention. Work status is described as permanent and stationary. A request for topical analgesic, Tramadol, Theramine, MRI of the thoracic spine, and 12 physical therapy sessions has been submitted.

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

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

**Flurbiprofen 20%/Lidocaine 5%/Amitriptyline 180gram:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

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

**Decision rationale:** According to the CA MTUS Chronic Pain Medical Treatment Guidelines topical analgesics are recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. The compound topical agent that contains Flurbiprofen, Amitriptyline, and Lidocaine. According to the guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen and Amitriptyline agents are not currently FDA approved for a topical application. In addition, topical lidocaine, only in the form of the Lidoderm patch is recommended. Therefore, any topical agent with lidocaine is not recommended if it is not Lidoderm. In this case, there is no documentation that the injured worker has failed a trial of oral antiepileptic and antidepressant medications to support the use of topical analgesics as required by the CA MTUS. In addition, the guidelines note that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen and Amitriptyline are not FDA approved for topical application and not outlined in the CA MTUS guidelines. Furthermore, the guidelines recommend topical lidocaine, only in the form of the Lidoderm patch. Therefore, based on MTUS guidelines and submitted medical records, the request for topical analgesic application is not medically necessary.

**Tramadol 50mg #80:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain, Opioids, specific drug list, Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC].

**Decision rationale:** Per the CA MTUS Chronic Pain Medical Treatment Guidelines, Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. The guidelines indicate continued use of opioids requires ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, the submitted medical records failed to provide ongoing monitoring of the 4 A's, which include detailed pain levels (baseline, average, least, and worst). These are necessary to meet the CA MTUS guidelines. In addition, the records do not establish that drug screening has been performed or that issues of abuse, addiction, or poor pain control have been addressed. As noted in the references, opioids may be continued if the patient has returned to work and has improvement in functioning and pain. There is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result. The work status is described as 'permanent and stationary', which implies a complete lack of functional improvement. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Tramadol is not medically necessary.

**Theramine #90:** Upheld

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

**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:** The CA MTUS guidelines are silent regarding the use of Theramine. However, according to the Official Disability Guidelines (ODG), Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food that 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 (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors. In this case, the submitted medical records failed to provide documentation regarding nutritional deficiency that would support the use of Theramine supplementation. Therefore, based on the Official Disability Guidelines and submitted medical records, the request for Theramine is not medically necessary.

**12 Physical Therapy Sessions, three (3) times a week for four (4) weeks for the Cervical Spine, Thoracic Spine, Lumbar Spine, Left Elbow and Left Wrist: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back, Procedures Summary, Physical Therapy, Hand Therapy.

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

**Decision rationale:** The CA MTUS Chronic Pain Medical Treatment Guidelines suggest physical medicine can be used sparingly with active therapies to help control swelling, pain and inflammation during the rehabilitation process. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. In this case, the guidelines state that medical necessity for any physical therapy beyond the initial course depends on functional improvement. The documentation supports the IW has undergone therapy sessions for the left hand and wrist. The work status is described as "permanent and stationary", which implies a complete lack of functional improvement. In addition, the injured worker should have had sufficient experience with physical therapy to perform independent exercise and self-care by now with previous physical therapy. Therefore, based on the CA MTUS guidelines and submitted medical records, the request for 12 physical therapy sessions to the cervical spine, thoracic spine, lumbar spine, left elbow, and left wrist is not medically necessary.

**MRI of the Thoracic Spine: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): Medical History, Physical Examination, Diagnostic Criteria, Special Studies.

**Decision rationale:** According to the CA ACOEM Medical Treatment Guidelines, special diagnostic studies are for patients presenting with true neck or upper back problems. Special studies are not needed unless a three- or four-week period of conservative care and observation fails to improve symptoms. Most patients improve quickly, provided any red-flag conditions are ruled out. Criteria for ordering imaging studies are: emergence of a red flag, physiologic evidence of tissue insult or neurologic dysfunction, failure to progress in a strengthening program intended to avoid surgery, and clarification of the anatomy prior to an invasive procedure. In this case, the submitted medical records failed to provide adequate clinical findings and/or presence of red flags to support diagnostic imaging of the thoracic spine. Therefore, based on ACOEM guidelines and submitted medical records, the request for MRI of the thoracic spine is not medically necessary.