

<b>Case Number:</b>	CM14-0005810		
<b>Date Assigned:</b>	02/05/2014	<b>Date of Injury:</b>	02/21/2011
<b>Decision Date:</b>	06/24/2014	<b>UR Denial Date:</b>	12/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/13/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 50-year-old male who was injured on 02/21/2011 while he was pushing a dolly down the stairs. He felt a pulling sensation in his lower back. The patient underwent a left-sided sacroiliac joint block under fluoroscopy guidance on 09/23/2013. The diagnostic studies reviewed include an MRI of the lumbar spine dated 09/27/2012, demonstrated 1) Early disc desiccation noted at L5-S1 level; 2) L4-L5 shows a diffuse disc protrusion with left preponderance effacing the thecal sac; 3) Bilateral neuroforaminal narrowing that effaces the left and right L4 exiting nerve roots, more so on the left side than the right; and 4) L5-S1 shows a diffuse disc protrusion with left preponderance without effacement of the thecal sac; Narrowing of the left neural foramen that effaces the left L5 exiting nerve root. An MRI of the right hip dated 09/27/2012, shows hypertrophy of right piriformis muscle, likely to result in piriformis syndrome. The pain management re-evaluation dated 12/02/2013, states that the patient complained of lumbar spine pain. Since his last visit, he reports he is better. He is not working, and has completed all of his sessions of physiotherapy. He is taking his tramadol as prescribed. He reported that he did get good relief from the compounds. His left leg pain, left knee pain, and low back pain is sharp in nature. On exam, the range of motion of the dorsolumbar spine exhibits flexion to 55 degrees and extension to 20 degrees. Lateral bending to 20 bilaterally and rotation to 35 bilaterally. The patient continues to have decreased range of motion of the lumbar spine with tenderness over the L4-L5 and L5-S1, greater on the left than on the right and over the left sacroiliac (SI) articulation. Straight leg raise is at 80 degrees bilaterally. Diagnostic impressions are left-sided sacroiliac joint arthropathy and lumbar spine sprain/strain with an MRI finding of disc protrusions at L4-L5 and L5-S1. The treatment and plan include Ultracet, amitriptyline, tramadol, dextromethorphan for neurolytic pain, and gabapentin/ketoprofen/Lidoderm compound. The prior utilization review (UR) dated

12/30/2013, states that the request for Ultracet, amitriptyline, tramadol, dextromethorphan for neurolytic pain, and gabapentin/ketoprofen/Lidoderm compound is non-certified as there is no pain contract in records provided. There is no evidence documenting effects of Ultracet, functional improvement or benefit. These drugs are not supported by medical evidence based guidelines.

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

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

#### **ULTRACET 37.5MG, QTY: 60.00: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, OPIOIDS, 89

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, OPIOIDS FOR CHRONIC PAIN Page(s): 74-96.

**Decision rationale:** The Chronic Pain Guidelines indicate that Tramadol (Ultram®) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic, it is indicated for moderate to severe pain. The guidelines also indicate that four (4) 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)." According to the medical records, the patient has not returned to work. There is no evidence that notable pain relief and functional improvement have been obtained as result of ongoing use of Ultracet. There is no indication that regular assessment of non-opioid and non-pharmacologic means of pain management have been done. The guidelines state that opioids may be continued: (a) if the patient has returned to work and (b) if the patient has improved functioning and pain. The medical records have not demonstrated the requirements per the guidelines, for continued opioid therapy have been met. The medical necessity for Ultracet has not been established. The request is not medically necessary.

#### **COMPOUND AMITRIPTYLINE/TRAMADOL/DEXTROMETHORPHAN, QTY: 1.00: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, TOPICAL ANALGESICS, 111-113

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** The Chronic Pain Guidelines indicate that topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for

pain control (including non-steroidal anti-inflammatory drugs (NSAIDs), opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\alpha$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many of these agents. The patient tolerates oral medications. He does not have a neuropathic pain condition. In addition, the records provided fail to establish any of the ingredients in topical formulation, are medically necessary for the management of this patient's complaints. The medical records do not provide a rationale that establishes the medical necessity for a compounded topical containing a cough suppressant, antidepressant and synthetic opioid in a topical compound. The requested compounded agent is not medically necessary.

**COMPOUND GABAPENTIN/KETOPROFEN/LIDODERM, QTY: 1.00:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, TOPICAL ANALGESICS,

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** The Chronic Pain Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state gabapentin is not recommended for topical formulations. There is no support to use gabapentin in a topical form. Ketoprofen is not FDA-approved for a topical application. It has an extremely high incidence of photo contact dermatitis. The guidelines state that only Lidocaine in the formulation of Lidoderm patch may be considered for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). The guidelines state no other commercially approved topical formulations of lidocaine are indicated for neuropathic pain. Only FDA-approved products are currently recommended. The guidelines states that any compounded product that contains at least one (1) drug (or drug class) that is not recommended is not recommended. It appears that all the components of this product are not recommended under the guidelines. Therefore, the requested topical compounded product is not supported as medically necessary.