

<b>Case Number:</b>	CM15-0041561		
<b>Date Assigned:</b>	05/01/2015	<b>Date of Injury:</b>	08/15/2011
<b>Decision Date:</b>	07/08/2015	<b>UR Denial Date:</b>	02/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/04/2015

### 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, Tennessee  
 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 45-year-old female, who sustained an industrial injury on 8/15/2011. She reported low back pain. The injured worker was diagnosed as having left knee medial meniscus tear, lumbar facet arthropathy, lumbar spinal stenosis, lumbar sprain, and lumbar lumbosacral disc degeneration, enthesopathy of hip, lumbago, and hemarthrosis. Treatment to date has included medications, magnetic resonance imaging, and lumbar epidural steroid injection. The request is for Tramadol/APA, CM3 Ketoprofen, Ultracet, physical therapy, and Ketoprofen cream. The records indicate she had increased low back pain initially with lumbar epidural steroid injection, and then it was reported to be somewhat helpful. On 2/11/2015, she complained of left knee pain, indicating she had had the pain since August 2011. She reported having had physical therapy for the knee. She rated her pain as 4/10. The treatment plan included: Tramadol/APAP, Lidopro topical ointment, blood work, follow up in 8 weeks, physical therapy, medial branch block, and urine drug screen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol/APAP 37. 5/325mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74-83. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) TWC 2013 Pain Chapter p 1393.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 11, 74-96.

**Decision rationale:** Tramadol/APAP is the compounded medication containing tramadol and acetaminophen. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDS have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. In this case, the patient has been receiving tramadol/APAP since at least October 2014 and has not obtained analgesia. In addition there is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. The request is not medically necessary.

**CM3 Ketoprofen 20%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

**Decision rationale:** Topical NSAIDS have been shown to be superior to placebo in the treatment of osteoarthritis, but only in the short term and not for extended treatment. The effect appears to diminish over time. Absorption of the medication can occur and may have systemic side effects comparable to oral form. Adverse effects for GI toxicity and renal function have been reported. It has not been evaluated for treatment of the spine, hip, or shoulder. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Topical ketoprofen is not recommended due to adverse effects. The request is not medically necessary.

**Ultracet 37.5mg every 6 hours PRN #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial

Approaches to Treatment Page(s): 47.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 11, 74-96.

**Decision rationale:** Ultracet is the compounded medication containing tramadol and acetaminophen. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDS have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. In this case the patient has been receiving Ultracet since at least October 2014 and has not obtained analgesia. In addition there is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. The request is not medically necessary.

**Ketoprofen Cream:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

**Decision rationale:** Topical NSAIDS have been shown to be superior to placebo in the treatment of osteoarthritis, but only in the short term and not for extended treatment. The effect appears to diminish over time. Absorption of the medication can occur and may have systemic side effects comparable to oral form. Adverse effects for GI toxicity and renal function have been reported. It has not been evaluated for treatment of the spine, hip, or shoulder. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Topical ketoprofen is not recommended due to adverse effects. The request is not medically necessary.

**Physical Therapy 2x6 for Lumbar Stabilization and IT Band Syndrome:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 98-99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 98-99.

**Decision rationale:** Chronic Pain Medical Treatment Guidelines state that there is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as traction, heat/cold applications, massage, diathermy, TENS units, ultrasound, laser treatment, or biofeedback. They can provide short-term relief during the early phases of treatment. Active treatment is associated with better outcomes and can be managed as a home exercise program with supervision. ODG states that physical therapy is more effective in short-term follow up. Patients should be formally assessed after a "six-visit clinical trial" to see if the patient is moving in a positive direction, no direction, or a negative direction (prior to continuing with the physical therapy). When treatment duration and/or number of visits exceed the guideline, exceptional factors should be noted. Recommended number of visits for myalgia and myositis is 9-10 visits over 8 weeks; and for neuralgia, neuritis, and radiculitis is 8-10 visits over 4 weeks. In this case, the patient has had prior chiropractic treatment and physical therapy with no documentation of objective evidence of functional improvement. In addition the requested number of 12 visits surpasses the number of six recommended for clinical trial to determine functional improvement. The request is not medically necessary.