

<b>Case Number:</b>	CM15-0135973		
<b>Date Assigned:</b>	07/24/2015	<b>Date of Injury:</b>	07/26/2014
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	07/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/14/2015

### 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: Internal 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 37 year old male, who sustained an industrial injury on 7/26/2014. The mechanism of injury is unclear. The injured worker was diagnosed as having lumbosacral musculoligamentous strain and sprain, lumbar disc protrusion with annular tear, lumbar radiculitis, and history of diabetes. Treatment to date has included physical therapy, medications, x-ray of the lumbar spine (5/19/2015), electrodiagnostic studies (4/22/2015). The request is for Tramadol, and compound medication: Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone micro 0.2%, and Capsaicin 0.025%, Hyaluronic acid 0.2%, 210 grams. Several pages of the medical records have handwritten information which is difficult to decipher. On 3/4/2015, he is placed on modified restricted duty work status. He complained of continued low back pain. He is planning on getting the approved epidural steroid injection. He continues to take Tylenol #3 as needed. The treatment plan included: chiropractic care, non-steroidal anti-inflammatory drugs as needed and epidural steroid injection in 2 weeks. On 3/12/2015, he complained of low back pain. The treatment plan included: Tramadol, Cyclobenzaprine, Naproxen, compound topical medications, hot and cold unit, and electrodiagnostic studies. On 4/22/2015, he complained of low back pain with radiation into the upper back and bilateral lower extremities. He rated the pain 6/10, and indicated he has numbness and tingling in the thighs and calves, and cramping and weakness in the thighs and legs. The electrodiagnostic studies performed were indicated to be normal. On 5/21/2015, he complained of low back pain with radiation. He rated his pain 6/10 and indicated it to be the same as his previous visit. Tenderness of the low back is noted on examination, along with a positive straight leg raise test. The treatment plan included: continued physical therapy, Tramadol, and compound medication: Flurbiprofen 20%, Baclofen 5%, Camphor 2%,

Menthol 2%, Dexamethasone micro 0.2%, and Capsaicin 0.025%, Hyaluronic acid 0.2%, 210 grams, and referral to pain management. On 6/25/2015, it is noted that he felt physical therapy helped to decrease his pain and tenderness, and his activities of daily living had improved by 20-40%. The treatment plan included: continued physical therapy, Tramadol, and compound medication: Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone micro 0.2%, and Capsaicin 0.025%, Hyaluronic acid 0.2%, 180 grams, and urine toxicology testing, and pain management referral. The provider indicated topical medications had been prescribed to minimize possible neurovascular complications, avoid complications with the use of narcotic medications as well as upper gastrointestinal bleeding from the use of non-steroidal anti-inflammatory medications. He is indicated to be temporarily totally disabled.

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

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

**60 tablets of Tramadol 50mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 60, 78, and 124.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids; Tramadol (Ultram); MTUS (2009), Functional restoration approach to chronic pain management Page(s): 113, 124, 74-95, 1, 8-9.

**Decision rationale:** Per the CA MTUS, Tramadol (Ultram) is a synthetic opioid affecting the central nervous system that is not recommended as a first line oral analgesic. The CA MTUS indicates the 4 A's for ongoing monitoring should be documented for analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. The CA MTUS indicates opioids for neuropathic pain are not recommended as a first line therapy. Opioid analgesics and Tramadol have been suggested as a second line treatment (alone or in combination with first line drugs). The MTUS recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. The CA MTUS Chronic Pain Medical Treatment Guidelines indicates that management of opioid therapy should include 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. According to the CA MTUS all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit,; and a reduction in the dependency on continued

medical treatment. In this case, he indicated that physical therapy helped his pain, and that his activities of daily living had improved by 20-40%. The records do not elaborate further on the activities of daily living. The records do not indicate his current level of pain; his least reported pain over the period since his last assessment; his average pain with the use of Tramadol; the intensity of his pain after taking Tramadol; how long it takes for his pain relief to occur with the use of Tramadol; and how long his pain relief lasts with the use of Tramadol. There is no indication of any known side effects with the use of Tramadol, or documentation regarding aberrant drug behaviors. The provider noted request authorization for urine toxicology testing; however there are no results or reports available for this review. He is indicated to be temporarily totally disabled. The records do not indicate an opioid contract has been signed. Based on these findings, it is determined that the request for 60 tablets of Tramadol 50mg is not medically necessary.

**1 compound medication (Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone Micro 0.2%, Capsaicin 0.025%, Hyaluronic Acid 0.2%) 210 grams:**

Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113, 105, and 28. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=hyaluronic+acid>.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Topical Analgesics; Capsaicin, topical; NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 111-113, 28, 72. Decision based on Non-MTUS Citation Drugs.com - Dexamethasone; MedicineNet.com - Hyaluronic acid.

**Decision rationale:** Per the CA MTUS, topical analgesics are recommended as an option. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended when trials of anticonvulsants and antidepressants have failed. The CA MTUS guidelines do not recommend any compounded product that contains at least one drug (or drug class) that is not recommended. Flurbiprofen is considered to be an NSAID (non-steroidal anti-inflammatory drug). Topical creams containing NSAIDs per MTUS may be recommended for short term for osteoarthritis and tendinitis. Topical NSAIDs are not recommended for osteoarthritis of the spine, hip, or shoulder. Baclofen is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Orally, Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non- FDA approved). As a topical agent Baclofen is not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. The CA MTUS and ODG guidelines do not discuss Menthol or Camphor. Per Drugs.com, Dexamethasone is a corticosteroid that is used to treatment many different inflammatory conditions such as allergic disorders, skin conditions, ulcerative colitis, arthritis, lupus, psoriasis, or breathing disorders. Per the CA MTUS oral corticosteroids are not recommended for managing low back complaints. The CA MTUS states that topical Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Per MedicineNet.com, Hyaluronic acid, is used

for the correction of moderate to severe wrinkles and folds, and is also used to enhance fullness of the lips. The CA MTUS and ODG guidelines do not discuss Hyaluronic acid. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. The requested compound medication of Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone Micro 0.2%, Capsaicin 0.025%, Hyaluronic Acid 0.2%, contains one or more ingredients that is not recommended. Therefore, the request for 1 compound medication (Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone Micro 0.2%, Capsaicin 0.025%, Hyaluronic Acid 0.2%) 210 grams is not medically necessary.