

<b>Case Number:</b>	CM14-0163947		
<b>Date Assigned:</b>	10/08/2014	<b>Date of Injury:</b>	07/17/2012
<b>Decision Date:</b>	08/26/2015	<b>UR Denial Date:</b>	09/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/06/2014

### 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. 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 61 year old female who sustained an industrial/work injury on 7/17/12. She reported an initial complaint of neck, shoulders, and low back pain. The injured worker was diagnosed as having cervical discopathy, bilateral shoulder impingement syndrome, bilateral upper extremity overuse tendinopathy, L4-5 disc herniation with bilateral intermittent radiculopathy, anxiety, and depression. Treatment to date includes medication and diagnostics. Currently, the injured worker complained of neck pain with numbness rated 9/10, bilateral shoulder pain rated 8/10, and bilateral wrist pain with pins and needles sensation rated 9/10. Per the primary physician's report (PR-2) on 8/22/14, exam noted limping gait, using a cane on the left side, right leg neuropathic pain. The cervical spine has painful extension, mildly positive compression sign, tightness in the levator scapula musculature, knot of muscle in a trigger area along the medial trapezius and upper levator scapula of the shoulder blade. The lumbar exam noted abnormal toe/heel walk on the right, tenderness in the paraspinous musculature of the lumbar region on the right, limited range of motion, grade 4 plantar flexion and toe extensor on the right. Right sacroiliac tenderness is noted with compression, and positive straight leg raise on right at 60 degrees supine and 50 degrees seated. The requested treatments include Acupuncture twice a week for four weeks for the lumbar/cervical spine, TGHot Cream 240mg, Fluriflex Cream 240mg, and Tramadol/APAP 5/325mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Acupuncture twice a week for four weeks for the lumbar/cervical spine:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** Per Acupuncture Medical Treatment Guidelines p9, "(c) Frequency and duration of acupuncture or acupuncture with electrical stimulation may be performed as follows: (1) Time to produce functional improvement: 3 to 6 treatments. (2) Frequency: 1 to 3 times per week. (3) Optimum duration: 1 to 2 months. (d) Acupuncture treatments may be extended if functional improvement is documented as defined in Section 9792.20." The MTUS definition of functional improvement is as follows: "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 billed under the Official Medical Fee Schedule (OMFS) pursuant to sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment." Per the guidelines cited above, 6 treatments of acupuncture are recommended. The documentation submitted for review does not specify if this is initial or additional acupuncture. It appears to be an initial request, however, as it is in excess of the guideline recommended number of treatments. The request is not medically necessary.

**TGHot Cream 240mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-112.

**Decision rationale:** TGHot contains tramadol, gabapentin, menthol, camphor and capsaicin. Capsaicin may have an indication for chronic knee pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." As the injured worker has osteoarthritis of the knees, capsaicin may be indicated. Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." The MTUS is silent on the use of tramadol and camphor topically. However, note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given

for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. As gabapentin is not recommended, the compound is not medically necessary.

### **Fluriflex Cream 240mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 60, 111-112.

**Decision rationale:** Fluriflex contains flurbiprofen and cyclobenzaprine. Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Per MTUS CPMTG p113, "There is no evidence for use of any other muscle relaxant as a topical product. [besides baclofen, which is also not recommended]" Cyclobenzaprine is not indicated. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications 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 anti-convulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each

medication individually. Because topical cyclobenzaprine is not indicated, the compound is not recommended. This request is not medically necessary.

**Tramadol/APAP 5/325mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 81. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-112.

**Decision rationale:** Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding ongoing management of opioids "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 nonadherent) drug related behaviors. These domains have been summarized as the 4 A's (Analgesia, activities of daily living, adverse side effects, and any 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." Review of the available medical records reveals no documentation to support the medical necessity of Ultracet nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. The submitted medical records contain numerous UDS reports, the latest available was dated 6/2014 and was negative for tramadol, which was prescribed. Prior UDS were consistent with tramadol use. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed. The request is not medically necessary.