

<b>Case Number:</b>	CM15-0054853		
<b>Date Assigned:</b>	03/30/2015	<b>Date of Injury:</b>	09/01/2014
<b>Decision Date:</b>	10/06/2015	<b>UR Denial Date:</b>	03/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/23/2015

### 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: 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 60 year-old male who sustained an industrial injury on 09/01/14. He reported neck and low back pain status post fall. Diagnoses include lumbar disc protrusion, lumbar radiculopathy, and depression. Diagnostic testing and treatment to date has included MRI of the cervical and lumbar spine, laboratory toxicology screening, chiropractic care, and acupuncture, thermotherapy, and pain medication management. Currently, the injured worker complains of constant, moderate, sharp low back pain. He is suffering from depression. Physical examination is remarkable for tenderness to palpation of the lumbar paravertebral muscles with muscle spasms; straight leg raise is positive bilaterally. Requested treatments include pharmacy purchase of capsaicin 0.025%/flurbiprofen 15%/Gabapentin 10%/menthol 2%/camphor 2% 180 grams #1, Gabapentin 15%/Amitriptyline 4%/dextromethorphan 10% 180 grams #1, rental of TENS unit, purchase of a lumbar brace and traction system, outpatient EMG/NCS, neurosurgery consultation, functional capacity evaluation, urine analysis testing, and physiotherapy therapy sessions to the low back, twice weekly for six weeks. The injured worker is under temporary total disability. Date of Utilization Review: 03/18/15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pharmacy purchase of Capsaicin 0.025%/Flurbiprofen 15%/Gabapentin 10%/Menthol 2%/Camphor 2% 180 grams #1: 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): Topical Analgesics.

**Decision rationale:** The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. 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. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.

**Gabapentin 15%/Amitriptyline 4%/Dextromethorphan 10% 180 grams #1: 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): Topical Analgesics.

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of gabapentin is stated to be not indicated for use for the patient's condition. The guidelines state the following: "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." As such, the request is not medically necessary.

**Rental of TENS/EMS unit: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar the thoracic/TENS (transcutaneous electrical nerve stimulation).

**Decision rationale:** The request is for the use of TENS unit therapy to aid in low back pain. The ODG state the following regarding this topic: Not recommended as an isolated intervention, but a one-month home-based TENS trial may be considered as a noninvasive conservative option for chronic back pain, if used as an adjunct to a program of evidence-based conservative care to achieve functional restoration, including reductions in medication use. Acute: Not recommended based on published literature and a consensus of current guidelines. No proven efficacy has been shown for the treatment of acute low back symptoms. (Herman, 1994) (Bigos, 1999) (Van Tulder, 2006) Chronic: Not generally recommended as there is strong evidence that TENS is not more effective than placebo or sham. (Airaksinen, 2006) There is minimal data on how efficacy is affected by type of application, site of application, treatment duration, and optimal frequency/intensity. (Brousseau, 2002) There are sparse randomized controlled trials that have investigated TENS for low back pain. One study of 30 subjects showed a significant decrease in pain intensity over a 60-minute treatment period and for 60 minutes after. (Cheing, 1999) A larger trial of 145 subjects showed no difference between placebo and TENS treatment. (Deyo, 1990) Single-dose studies may not be effective for evaluating long-term outcomes, or the standard type of use of this modality in a clinical setting. (Milne-Cochrane, 2001) (Sherry, 2001) (Philadelphia Panel, 2001) (Glaser, 2001) (Maher, 2004) (Brousseau, 2002) (Khadikar, 2005) (Khadikar 2, 2005) Although electrotherapeutic modalities are frequently used in the management of CLBP, few studies were found to support their use. Most studies on TENS can be considered of relatively poor methodological quality. TENS does not appear to have an impact on perceived disability or long-term pain. High frequency TENS appears to be more effective on pain intensity when compared with low frequency, but this has to be confirmed in future comparative trials. It is also not known if adding TENS to an evidence-based intervention, such as exercise, improves even more outcomes, but studies assessing the interactions between exercise and TENS found no cumulative impact. (Poitras, 2008) For more information, see the Pain Chapter. Recent research: A recent meta-analysis concluded that the evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of chronic LBP. There was conflicting evidence about whether TENS was beneficial in reducing back pain intensity and consistent evidence that it did not improve back-specific functional status. There was moderate evidence that work status and the use of medical services did not change with treatment. Patients treated with acupuncture-like TENS responded similarly to those treated with conventional TENS. (Khadikar-Cochrane, 2008) On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) issued an updated decision memo concluding that TENS is not reasonable and necessary for the treatment of chronic low back pain based on a lack of quality evidence for its effectiveness. Coverage is available only if the beneficiary is enrolled in an approved clinical study. (Jacques, 2012) As stated above the use of TENS therapy in low back pain is not indicated. There is a lack of quality evidence for its effectiveness. As such, the request is not medically necessary.

**Purchase of a lumbar brace:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS General Approaches 2004, Section(s): Prevention.

**Decision rationale:** The request is for the use of a lumbar back support to aid in pain relief and injury prevention. The ACOEM guidelines makes the following statement: "The use of back belts as lumbar support should be avoided because they have been shown to have little or no benefit, thereby providing only a false sense of security". As an alternative it is advised that prolonged sitting and standing should be reduced by providing rest and exercise breaks and task rotation and variation should be employed. Heavy loads need to be divided and mechanical support devices used. Also, the workstation can be set up to optimize reduction in back strain. As such, due to poor evidence of its utility and effectiveness, the request is not medically necessary.

**Rental of lumbar traction system:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic)/Traction.

**Decision rationale:** The request is for the use of a lumbar traction device. The Official Disability Guidelines state the following regarding this topic: Not recommended using powered traction devices, but home-based patient controlled gravity traction may be a noninvasive conservative option, if used as an adjunct to a program of evidence-based conservative care to achieve functional restoration. As a sole treatment, traction has not been proved effective for lasting relief in the treatment of low back pain. Traction is the use of force that separates the joint surfaces and elongates the surrounding soft tissues. (Beurskens, 1997) (Tulder, 2002) (Van Der Heijden, 1995) (Van Tulder, 2000) (Borman, 2003) (Assendelft-Cochrane, 2004) (Harte, 2003) (Clarke, 2006) (Clarke, 2007) (Chou, 2007) The evidence suggests that any form of traction may not be effective. Neither continuous nor intermittent traction by itself was more effective in improving pain, disability or work absence than placebo, sham or other treatments for patients with a mixed duration of LBP, with or without sciatica. There was moderate evidence that auto traction (patient controlled) was more effective than mechanical traction (motorized pulley) for global improvement in this population. (Clarke-Cochrane, 2005) Traction has not been shown to improve symptoms for patients with or without sciatica. (Kinkade, 2007) The evidence is moderate for home based patient controlled traction compared to placebo. (Clarke, 2007) A clinical prediction rule with four variables (non-involvement of manual work, low level fear- avoidance beliefs, no neurological deficit and age above 30 years) was identified. The presence of all four variables (positive likelihood ratio = 9.36) increased the probability of response rate with mechanical lumbar traction from 19.4 to 69.2%. (Cai, 2009) See also Powered traction devices; Vertebral axial decompression (VAX-D); IDD therapy (intervertebral disc decompression); & Orthrotrac vest. In this case, the use of this product is not indicated. This is secondary to non-certification of powered devices based on the guidelines. As such, the request is not medically necessary.

**Outpatient EMG/NCV:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar & Thoracic (Acute & Chronic)/Nerve conduction studies (NCS).

**Decision rationale:** The request is for nerve conduction studies. The ODG state the following regarding this study: Not recommended. There is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. (Utah, 2006) This systematic review and meta-analysis demonstrate that neurological testing procedures have limited overall diagnostic accuracy in detecting disc herniation with suspected radiculopathy. (Al Nezari, 2013) In the management of spine trauma with radicular symptoms, EMG/nerve conduction studies (NCS) often have low combined sensitivity and specificity in confirming root injury, and there is limited evidence to support the use of often uncomfortable and costly EMG/NCS. (Charles, 2013) See also the Carpal Tunnel Syndrome Chapter for more details on NCS. Studies have not shown portable nerve conduction devices to be effective. EMGs (electromyography) are recommended as an option (needle, not surface) to obtain unequivocal evidence of radiculopathy, after 1-month conservative therapy, but EMG's are not necessary if radiculopathy is already clinically obvious. In this case, the patient does not meet criteria for the study requested. This is secondary to radiculopathy already diagnosed in the records. Pending receipt of information further clarifying how this would change the management rendered, the study is not certified and therefore is not medically necessary.

**Neurosurgeon consultation:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Independent Medical Examinations and Consultations Chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 7), page 127, as well as the Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Surgical Considerations.

**Decision rationale:** The request is for specialty consultation. The ACOEM guidelines state the following regarding referral for surgical consultation: "Severe and disabling lower leg symptoms in a distribution consistent with abnormalities on imaging studies (radiculopathy), preferably with accompanying objective signs of neural compromise," Activity limitations due to radiating leg pain for more than one month or extreme progression of lower leg symptoms, "Clear clinical, imaging, and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair" Failure of conservative treatment to resolve disabling radicular symptoms. Based on the records the patient does have ongoing symptoms and failure of resolution with conservative therapy. There is inadequate documentation of physical exam findings of a change in the patient's neurologic exam or objective signs of neural compromise. As such, pending further information, the request is not certified and therefore is not medically necessary.

**Functional Capacity Evaluation (FCE):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fit for Duty/Functional capacity evaluation.

**Decision rationale:** The request is for a functional capacity evaluation. The MTUS guidelines are silent regarding this issue. The ODG state the following: Guidelines for performing an FCE: Recommended prior to admission to a Work Hardening (WH) Program, with preference for assessments tailored to a specific task or job. If a worker is actively participating in determining the suitability of a particular job, the FCE is more likely to be successful. A FCE is not as effective when the referral is less collaborative and more directive. It is important to provide as much detail as possible about the potential job to the assessor. Job specific FCEs are more helpful than general assessments. The report should be accessible to all the return to work participants. Consider an FCE if: 1) Case management is hampered by complex issues such as: "Prior unsuccessful RTW attempts", "Conflicting medical reporting on precautions and/or fitness for modified job", "Injuries that require detailed exploration of a worker's abilities," 2) Timing is appropriate: "Close or at MMI/all key medical reports secured", "Additional/secondary conditions clarified." Do not proceed with an FCE if "The sole purpose is to determine a worker's effort or compliance", "The worker has returned to work and an ergonomic assessment has not been arranged" (WSIB, 2003) In this case a functional capacity evaluation is not indicated. There is inadequate documentation of the patient and employer actively participating in determining the suitability of a particular job. As such, the request is not medically necessary.

**Urine analysis testing:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Urine drug testing (UDT).

**Decision rationale:** The request is for a urine drug screen. The ODG states the following regarding this topic: Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain). (2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or 'at risk' addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected.

See Opioids, indicators for addiction & misuse. Ongoing monitoring: (1) If a patient has evidence of a 'high risk' of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. In this case, a urine drug screen is not supported by the guidelines. This is secondary to inadequate documentation of risk level commensurate to the frequency of evaluation requested. As such, it is not medically necessary.

**Physiotherapy therapy sessions to the low back, twice weekly for six weeks:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Manual therapy & manipulation.

**Decision rationale:** The request is for physical therapy to aid in pain relief. The MTUS guidelines states that manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. It is indicated for low back pain but not ankle and foot conditions, carpal tunnel syndrome, forearm/wrist/hand pain, or knee pain. The use of active treatment modalities instead of passive treatments is associated with substantially better clinical outcomes. (Fritz, 2007) Active treatments also allow for fading of treatment frequency along with active self-directed home PT, so that less visits would be required in uncomplicated cases. In this case, the patient would benefit most from at home active therapy. As such, the request is not medically necessary.