

<b>Case Number:</b>	CM15-0107331		
<b>Date Assigned:</b>	07/20/2015	<b>Date of Injury:</b>	12/20/2013
<b>Decision Date:</b>	10/13/2015	<b>UR Denial Date:</b>	05/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/03/2015

### 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 28 year old female who sustained an industrial injury on December 20, 2013. She has reported neck pain, left shoulder pain, mid back pain, radicular low back pain, and bilateral knee pain and has been diagnosed with cervicgia, rule out cervical spine herniated nucleus pulposus, left shoulder sprain and strain rule out internal derangement, thoracic spine pain, thoracic sprain and strain rule out herniated nucleus pulposus, low back pain, lumbar spine sprain and strain rule out herniated nucleus pulposus, rule out lumbar radiculopathy, and bilateral knee sprain and strain rule out internal derangement. Treatment has included medical imaging, chiropractic care, and medications. There was tenderness of the cervical spine with decreased range of motion. There was tenderness of the left shoulder with decreased range of motion. There was palpable tenderness over the thoracic spine with normal range of motion. There was palpable tenderness over the lumbar spine with decreased range of motion. There was tenderness to palpation over the medial and lateral joint line and to the patellofemoral joint bilaterally. Range of motion was within normal limits. The treatment request included Ketoprofen, Flexeril, synapryn, Tabradol, deprizine, Dicopanol, Fanatrex, MRI of the cervical spine, pain management, orthopedic surgeon consultation, shockwave therapy, and Terocin patches.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% Cream, 167gm: 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 lend 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.

**Cyclobenzaprine 5% Cream, 110gms: 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 the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following: "There is no evidence for use of any other muscle relaxant as a topical product." As such, the request is not medically necessary.

**Synapryn 10gm/1ml, 550ml: 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): Opioids for chronic pain.

**Decision rationale:** Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short-term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of Tramadol for osteoarthritis is indicated for short-term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

**Tabradol 1mg/ml, 250ml:** 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) Pain (Chronic)/NSAIDs, specific drug list & adverse effects.

**Decision rationale:** The request is for the use of Ketorolac intramuscular injection for pain relief. The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose. (Toradol Package Insert) The FDA has approved a nasal formulation of Ketorolac (Sprix) for short-term pain management. (FDA, 2010) As indicated above, this patient does not qualify for the use of Ketorolac. This is secondary to the duration of use with the guidelines stating that it is not to be given for chronic painful conditions. As such, the request is not medically necessary.

**Deprizine 15mg/ml, 250ml:** 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): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The request is for the use of a medication in the class of an acid reducing medication. The guidelines do not specifically address or advise the use of an H2 blocker but does make recommendations regarding medications in the same category classified as proton pump inhibitors. This is usually given for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain, which have side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically with a proton pump inhibitor or Misoprostol. Criteria for risk are as follows: "(1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

**Dicopanol 5mg/ml, 150ml:** 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) Mental Illness and Stress/Diphenhydramine (Benadryl).

**Decision rationale:** The request is for the use of Diphenhydramine, which is in the category of an antihistamine. The MTUS guidelines are silent regarding this topic. The ODG states the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes diphenhydramine. (AGS, 2012) Anticholinergic drugs, including diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anticholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated for use in this patient for insomnia. There is inadequate documentation of the reasoning for its use for other indications. As such, the request is not medically necessary.

**Fanatrex 25mg/ml, 420ml:** 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): Anti-epilepsy drugs (AEDs).

**Decision rationale:** The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials, which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There should be documentation of functional improvement and side effects incurred with use. Disease states, which prompt use of these medications, include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

**MRI of the Cervical Spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Neck and Upper Back Complaints 2004.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and upper back complaints/MRI.

**Decision rationale:** The request is for an MRI of the thoracic spine. The ACOEM guidelines state that when there is physiological evidence of tissue insult or neurological deficits, consider a discussion with a consultant regarding the next steps including MRI imaging. An imaging study may be appropriate in patients where symptoms have lasted greater than 4-6 weeks and surgery is being considered for a specific anatomic defect or to further evaluate the possibility of serious pathology, such as a tumor. Reliance on imaging studies alone to evaluate the source of neck or upper back symptoms carries a significant risk of diagnostic confusion (false-positive test results) because it's possible to identify a finding that was present before symptoms began and, therefore, has no temporal association with the symptoms. The ODG guidelines regarding qualifying factors for an MRI of the neck or upper back are as follows: Indications for imaging-MRI (magnetic resonance imaging): Chronic neck pain (after 3 months conservative treatment), radiographs normal, neurologic signs or symptoms present. Neck pain with radiculopathy if severe or progressive neurologic deficit. Chronic neck pain, radiographs show spondylosis, neurologic signs or symptoms present. Chronic neck pain, radiographs show old trauma, neurologic signs or symptoms present. Chronic neck pain, radiographs show bone or disc margin destruction. Suspected cervical spine trauma, neck pain, clinical findings suggest ligamentous injury (sprain), radiographs and/or CT "normal". Known cervical spine trauma: equivocal or positive plain films with neurological deficit. Upper back/thoracic spine trauma with neurological deficit. In this case, there is inadequate documentation in a change in neurologic status seen on exam. The records do not indicate new "red flags" which would warrant further

imaging evaluation. Pending further information regarding new neurologic deficits, the request is not medically necessary.

**Pain Management Consultation:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain Disorder Medical Treatment Guidelines, State of Colorado Department of Labor and Employment (Chapter: Chronic Pain Disorder, Section: Therapeutic Procedures, Non-Operative), 4/27/2007, pg 56.

**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)/Office Visits.

**Decision rationale:** The request is for a pain management consultation. The MTUS guidelines do not address this issue specifically. The ODG state the following regarding this topic. Recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from the health care system through self care as soon as clinically feasible. The ODG Codes for Automated Approval (CAA), designed to automate claims management decision-making, indicates the number of E&M office visits (codes 99201-99285) reflecting the typical number of E&M encounters for a diagnosis, but this is not intended to limit or cap the number of E&M encounters that are medically necessary for a particular patient. Office visits that exceed the number of office visits listed in the CAA may serve as a "flag" to payors for possible evaluation, however, payors should not automatically deny payment for these if preauthorization has not been obtained. Note: The high quality medical studies required for treatment guidelines such as ODG provides guidance about specific treatments and diagnostic procedures, but not about the recommended number of E&M office visits. Studies have and are being conducted as to the value of "virtual visits" compared with inpatient visits, however the value of patient/doctor interventions has not been questioned. (Dixon, 2008) (Wallace, 2004) Further, ODG does provide guidance for therapeutic office visits not included among the E&M codes, for example Chiropractic manipulation and Physical/Occupational therapy. See also Telehealth. In this case, the request is reasonable and supported by the documentation. The patient has chronic pain, which justifies evaluation by a pain management specialist. As such, the request is medically necessary.

**Orthopedic Surgeon Consultation:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Knee Complaints 2004.

**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 medically necessary.

**Shockwave Therapy (6-sessions for the cervical spine): 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) Neck and Upper Back (Acute & Chronic)/ Extracorporeal shock wave therapy (ESWT).

**Decision rationale:** The request is for extracorporeal shock wave therapy (ESWT) of the neck to aid in pain relief. The Official Disability Guidelines state the following regarding this topic: Not recommended for back pain. The available evidence does not support the effectiveness of shock wave for treating back pain. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. (Seco, 2011) See the Low Back Chapter. Two small studies have been published for upper back or neck pain. In this study, trigger point treatment with radial shock wave used in combination with physical therapy provided temporary relief of neck and shoulder pains, but the effects of radial shock wave without physical therapy need to be examined in further studies. (Damian, 2011) In this study ESWT in patients with myofascial pain syndrome in trapezius muscle were as effective as trigger point injections (TPI) and TENS for pain relief and improving cervical range of motion, but neither TENS nor TPI are recommended treatments. (Jeon, 2012) In this case, the use of this treatment is not indicated. This is secondary to poor clinical evidence of efficacy per the guidelines. As such, the request is not medically necessary.

**Shockwave Therapy (3-sessions for the left shoulder and bilateral knees): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Shoulder Complaints 2004.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg/Extracorporeal shock wave therapy (ESWT).

**Decision rationale:** The request is for extracorporeal shock wave therapy (ESWT) to aid in pain relief. The Official Disability Guidelines state the following regarding this topic: Under study for patellar tendinopathy and for long-bone hypertrophic non-unions. In the first study of this therapy for management of chronic patellar tendinopathy, extracorporeal shockwave therapy seemed to be safer and more effective, with lower recurrence rates, than conventional conservative treatments, according to results of a recent small, randomized controlled trial. (Wang, 2007) New research suggests that extracorporeal shock-wave therapy (ESWT) is a viable alternative to surgery for long-bone hypertrophic non-unions. However, the findings need to be verified, and different treatment protocols as well as treatment parameters should be investigated, including the number of shock waves used, the energy levels applied and the frequency of application. (Cacchio, 2009) New data presented at the American College of Sports Medicine Meeting suggest that extracorporeal shockwave therapy (ESWT) is ineffective for treating patellar tendinopathy, compared to the current standard of care emphasizing multimodal physical therapy focused on muscle retraining, joint mobilization, and patellar taping. (Zwerver, 2010) In this case, the use of this treatment modality is not indicated. This is secondary to poor clinical evidence regarding effectiveness for the patient's condition. As such, the request is not medically necessary.

**Shockwave Therapy (6-sessions for the thoracic and lumbar spine):** 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) Low Back Lumbar & Thoracic (Acute & Chronic)/ Extracorporeal shock wave therapy (ESWT).

**Decision rationale:** The request is for extracorporeal shock wave therapy (ESWT). The MTUS guidelines has limited information regarding this topic for back pain. The Official Disability Guidelines state the following: Not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. (Seco, 2011) In this case, the use of this treatment modality is not indicated. This is secondary to poor clinical evidence regarding effectiveness of use. As such, the request is not medically necessary.

**Terocin Patches:** 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 Lidoderm patch to aid in pain relief. The MTUS guidelines state that its use is indicated for post herpetic neuralgia after an initial trial of an anti-epileptic medication. Further research is needed to recommend use for chronic neuropathic disorders besides post-herpetic neuralgia. In this case, the patient does not have a diagnosis documented that would justify the use of Lidoderm patches. As such, the request is not medically necessary.