

<b>Case Number:</b>	CM15-0102053		
<b>Date Assigned:</b>	06/04/2015	<b>Date of Injury:</b>	12/15/2007
<b>Decision Date:</b>	07/08/2015	<b>UR Denial Date:</b>	04/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/27/2015

### 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: Colorado

Certification(s)/Specialty: Family Practice

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 59 year old female with a December 15, 2007 date of injury. A progress note dated April 16, 2015 documents subjective findings (increased neck pain and headaches; moderate to severe neck pain; mild right shoulder pain; moderate left shoulder pain; moderate right wrist pain; mild left wrist pain; moderate lower back pain), objective findings (tenderness of both scapulae, right worse than left; decreased range of motion of the cervical spine; decreased right grip strength; positive straight leg raises bilaterally), and current diagnoses (cervical disc herniation with reversal of cervical curvature; severe depression secondary to chronic pain; bilateral posttraumatic arthritis of the carpometacarpal joints of the thumbs; bilateral shoulder impingement syndrome; lumbar L5-S1 degenerative joint disease and first degree spondylolisthesis with herniated nucleus pulposus with nerve root impingement; insomnia; chronic thoracic sprain/strain; bilateral carpal tunnel syndrome). Treatments to date have included epidural injections, medications, imaging studies, therapy, and diagnostic testing. The treating physician documented a plan of care that included Tramadol, topical creams (Ketoprofen, Gabapentin, and Tramadol), X-force with Solar Care Device, and referral to an orthopedic surgeon.

### IMR ISSUES, DECISIONS AND RATIONALES

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

## **Tramadol 150mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 78-80, 85, 88-89, and 93.

**Decision rationale:** Tramadol is a synthetic opioid that exerts its effect on the central nervous system. The MTUS Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated clinical assessment tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. 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. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids. 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function. 4) Patient has evidence of unacceptable side effects. 5) Patient's pain has resolved. 6) Patient exhibits "serious non-adherence" or misuse. Per the Guidelines, Chelminski defines "serious substance misuse" as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005) 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work? Has patient had improved function and decreased pain with the opioids? For the patient of concern, there is no documentation of sustained improvement in pain or objective improvement in function. There is no documentation of discussion of opioid side effects or aberrant drug taking behavior assessment. The records refer to monitoring of medications with urine drug screens, but the only urine drug screen report supplied is dated November 2014, and is negative for

prescribed medication Tramadol. There is no indication in the record that this inconsistent urine drug screen result was addressed or was to be followed up. Without evidence that opioid therapy is effective and appropriately monitored, the Tramadol is not approved as medically necessary.

**Tropical creams: Ketoprofen, Gabapentin, Tramadol: 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 Treatments Page(s): 111-113.

**Decision rationale:** Per the MTUS Guidelines, topical analgesics are largely experimental, but may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is "not recommended," then the entire topical treatment is not recommended. Topical Non-steroidal anti-inflammatory drugs have been studied, but only short term in small numbers, so no substantive evidence supports long-term use. Use of topical non-steroidal anti-inflammatory drugs can be recommended, after first line therapies fail, for less than 12 weeks, for treatment of osteoarthritis, specifically related to the knee or elbow. No consistent quality evidence exists to use topical non-steroidal anti-inflammatory drugs for treatment of osteoarthritis of the spine, hip or shoulder, or for treatment of neuropathic pain, including radiculopathy. The only FDA-approved Topical Non-steroidal anti-inflammatory agent is Voltaren Gel 1% (Diclofenac). Per the MTUS Guidelines, Gabapentin topical is not recommended. No studies support its use in topical preparations. The MTUS Guidelines do not address topical Tramadol specifically, which is not relevant as the MTUS does indicate that any topical preparation would only be indicated after failure of other therapies. For the patient of concern, the record does not indicate where the Topical Tramadol is to be applied / what is being treated and whether or not other treatments have been tried and failed. As the Ketoprofen is not an FDA approved topical non-steroidal anti-inflammatory drug, and as topical non-steroidal anti-inflammatory drugs in general are not to be used for longer than 12 weeks, the Ketoprofen for this patient is not medically necessary. As the Gabapentin has no support for its use in topical form, the request for Gabapentin is not medically necessary. As there is no documentation for the specific diagnosis for the use of topical Tramadol, and thus no indication of failure of first line therapies, the topical Tramadol is not medically necessary.

**MRI of cervical: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Minnesota Rules, 5221.6100 Parameters for Medical Imaging.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 4-5.

**Decision rationale:** MRI is recommended [Recommended, Evidence (C)] for patients with: Acute cervical pain with progressive neurologic deficit; Significant trauma with no improvement in significantly painful or debilitating symptoms; A history of neoplasia (cancer); Multiple neurological abnormalities that span more than one neurological root level; Previous neck surgery with increasing neurologic symptoms; Fever with severe cervical pain; Symptoms

or signs of myelopathy; or Subacute or chronic radicular pain syndromes lasting at least 4 to 6 weeks in whom dermatomal and myotomal symptoms are not trending towards improvement if either injection is being considered or both the patient and surgeon are considering early surgical treatment if supportive findings on MRI are found. MRI is not recommended for non-specific neck pain. MRI is not recommended for acute radiculopathy, unless patient has progressive neurological symptoms or severe impairment, and injections or early surgical intervention are being considered. For the patient of concern, the records do establish that patient has neurological deficits on exam and complaints that could be radicular on history, however these findings are not new for patient. While the Orthopedic surgeons have documented that patient needs surgery (as far back as early 2014) , there is no documentation that patient is willing to consider procedure. Based on the Guidelines and lack of evidence that patient is willing to proceed with procedure, repeat MRI of Cervical Spine is not medically necessary.

**X-force with Solar Care Device: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Page(s): 265, Chronic Pain Treatment Guidelines TENS Page(s): 114, 116. Decision based on Non-MTUS Citation ODG, Shoulder Chapter; <http://www.sevensesdm.com/force-stimulator/>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 114-116. Decision based on Non-MTUS Citation [www.sevensesdm.com/force-stimulator](http://www.sevensesdm.com/force-stimulator/).

**Decision rationale:** Per online source, the X-Force Stimulator with Solar Care device is an FDA approved proprietary dual modality unit, offering TEJS and TENS functions, that uses electrical stimulation to alleviate pain. The X-Force Stimulator is different from TENS units and other electrical stimulation devices, though it includes the same functions as TENS unit. As the X-Force stimulator includes TENS unit functions, the Guidelines recommendations regarding TENS units would apply. Per the Guidelines: Electrotherapy represents the therapeutic use of electricity and is another modality that can be used in the treatment of pain, though not recommended a primary modality. The earliest, and still most commonly used electrotherapy devices to apply current to the skin, are known as TENS (transcutaneous electrical nerve stimulation) units. A TENS unit can be one of several devices. (H-wave stimulation device, Interferential Current Stimulation, Microcurrent electrical stimulation or MENS devices, RS-4i sequential stimulator, Electroceutical Therapy, Neuromuscular electrical stimulation or NMES devices, Sympathetic therapy, and Dynatron STS) Though not recommended as first line treatment, a TENS unit may be considered for use as part of a functional restoration program for specific conditions. While use of TENS units continues to be standard of care in many communities, the evidence is lacking to establish effectiveness short term or long term. The Guidelines specify conditions in which TENS unit may be useful: Neuropathic pain: Some evidence (Chong, 2003), including diabetic neuropathy (Spruce, 2002) and post-herpetic neuralgia. (Niv, 2005) Phantom limb pain and CRPS II: Some evidence to support use. (Finsen, 1988) (Lundeberg, 1985) Spasticity: TENS may be a supplement to medical treatment in the management of spasticity in spinal cord injury. (Aydin, 2005) Multiple sclerosis (MS): While TENS does not appear to be effective in reducing spasticity in MS patients it may be useful in treating MS patients with pain and muscle spasm. (Miller, 2007) Recent evaluation of available studies on TENS unit use reveals that current studies lack quality methodology and evidence based conclusions, so TENS unit is not known to be effective in chronic musculoskeletal pain. The Guidelines establish criteria for TENS unit use: Pain for at least 3 months. Documentation that other therapies, including medications, have been tried, and failed. A one month trial of

TENS unit use should be in the record, as part of a functional restoration program, with frequency of use noted, as well as pain relief and functional improvement achieved. Other treatments ongoing during same time as the TENS units trial should be in the record. Goals of treatment with the TENS unit should be documented. (including long and short term goals) A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary. Form-fitting TENS device: For use in large area or because of skin condition or because TENS unit to be used under a cast. Post-operative use of TENS unit: Recommended for first 30 days after surgery. Per the records for the patient of concern, patient has not previously used a TENS unit. The records supplied for review did not include information on a TENS unit trial if one was conducted. Also, there is no documentation of the goals of treatment for the TENS unit / X-Force stimulator, or the inclusion of functional restoration program with TENS unit / X-force stimulator. As the X-Force stimulator is not documented to be used with a functional restoration program, and as there is no documentation of TENS unit trial for efficacy, the request for X-force stimulator, which includes TENS unit function, is not medically necessary.

**Referral to ortho surgeon:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Page(s): 127. Decision based on Non-MTUS Citation ODG, Low Back Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004), revised 2007 Chapters 6 and 10 pages 163, 803-804, 859-860.

**Decision rationale:** The MTUS Guidelines do not specifically address indications for consultation, so the ACOEM Guidelines were consulted. Per the ACOEM Guidelines, consultation is recommended when the patient's chronic pain condition is related to patient's poor function and no cause clearly evident. Consultation with a specialist can be used then to confirm diagnosis and/or devise treatment regimen. Consultants can also assist in assigning loss, assessing medical stability and determining fitness to return to work. The specialist may offer just advice / input or take over patient care for a given condition. The choice of specialist to consult will depend on the patient needs. (Medical, Physical, Psychological) For the patient of concern, the records indicate she is already in follow up with Orthopedic surgeon, and follow up with that Orthopedic surgeon has been approved. The requesting Orthopedic surgeon indicates patient has not seen the other Orthopedic surgeon consulted since 2011, when in fact she saw that Orthopedist in 2014 and recommendations at that time were unchanged from previous - surgery recommended. The most recent records indicate that patient previously unwilling to have surgery. The current records do not indicate that patient is now willing to consider surgery, so not clear why re-evaluation for surgery would be necessary. As the records do not indicate that patient willing to consider interventions previously recommended, additional Orthopedic evaluation in anticipation of surgery, would not be medically necessary.