MAXIMUS Federal Services

| Case Number: | CM15-0145126 | | |
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| Date Assigned: | 08/06/2015 | Date of Injury: | 11/14/2012 |
| Decision Date: | 09/29/2015 | UR Denial Date: | 07/16/2015 |
| Priority: | Standard | Application Received: | 07/27/2015 |

## 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: 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 44 year old male, who sustained an industrial injury on November 14, 2012. The injured worker reported working on a roof carrying materials when the wind caught the materials causing the injured worker to twist and fall with the weight on top of him. The injured worker was diagnosed as having hip or thigh strain, sacroiliac subluxation, lumbar sprain and strain, and elbow lateral epicondylitis. Treatment and diagnostic studies to date has included use of a use of a transcutaneous electrical nerve stimulation unit, home exercise program, medication regimen, x-rays, magnetic resonance imaging, and ultrasound massage therapy. In a progress note dated July 10, 2015 the treating physician reports complaints of pain to the low back and the right hip. Examination reveals tenderness to palpation and decreased range of motion. The injured worker's medication regimen included Gabapentin, Fenoprofen, and Lidopro Cream. The injured worker's pain level was rated a 5 out of 10, but the documentation provided did not indicate the injured worker's pain level as rated on a pain scale after use of his medication regimen to indicate the effects with the use of the injured worker's current medication regimen. The treating physician noted that the use of the injured worker's medication regimen and transcutaneous electrical nerve stimulation unit assisted with his pain, but the documentation provided did not indicate if the injured worker experienced any functional improvement with use of his medication regimen or transcutaneous electrical nerve stimulation unit. The progress note also indicated that the injured worker received ultrasound massage therapy to the lumbar spine with benefit, but the documentation provided did not indicate how many sessions and if the injured worker experienced any functional improvement with prior massage therapy. The treating physician requested the medications of Fenoprofen Calcium

400mg with a quantity of 60 with two refills, Gabapentin 100mg with a quantity of 60 with two refills, and Lidopro cream 120gm, noting current use of these medications as noted above. The treating physician also requested the medication Norco 5-325mg with a quantity of 60 to better assist with the injured worker's pain. The treating physician requested transcutaneous electrical nerve stimulation patches with a quantity of four noting current use of a transcutaneous electrical nerve stimulation unit as noted above. The treating physician requested massage therapy with ultrasound for treatment of the lumbar spine noting that the injured worker "felt comfortable" with past treatment. The treating physician also requested trigger point injections to the lumbar spine, but he documentation provided did not indicate the specific reason for the requested treatment.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Massage therapy (unspecified):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Massage therapy Page(s): 60.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 60 of 127.

**Decision rationale:** Recommended as an option as indicated below. This treatment should be an adjunct to other recommended treatment (e.g. exercise), and it should be limited to 4-6 visits in most cases. Scientific studies show contradictory results. Furthermore, many studies lack long-term follow-up. Massage is beneficial in attenuating diffuse musculoskeletal symptoms, but beneficial effects were registered only during treatment. Massage is a passive intervention and treatment dependence should be avoided. This lack of long-term benefits could be due to the short treatment period or treatments such as these do not address the underlying causes of pain. (Hasson, 2004) A very small pilot study showed that massage can be at least as effective as standard medical care in chronic pain syndromes. Relative changes are equal, but tend to last longer and to generalize more into psychologic domains. (Walach 2003) The strongest evidence for benefits of massage is for stress and anxiety reduction, although research for pain control and management of other symptoms, including pain, is promising. The physician should feel comfortable discussing massage therapy with patients and be able to refer patients to a qualified massage therapist as appropriate. (Corbin 2005) Massage is an effective adjunct treatment to relieve acute postoperative pain in patients who had major surgery, according to the results of a randomized controlled trial recently published in the Archives of Surgery. (Mitchinson, 2007)In this case, further massage therapy is not indicated. As stated above, this is secondary to previous therapy. The maximum number of treatments is 4-6. As such, the request is not medically necessary.

**Trigger point injections to the lumbar spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Trigger point injections Page(s): 122.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 122 of 127.

**Decision rationale:** Recommended only for myofascial pain syndrome as indicated below, with limited lasting value. Not recommended for radicular pain. Trigger point injections with an anesthetic such as Bupivacaine are recommended for non-resolving trigger points, but the addition of a corticosteroid is not generally recommended. Not recommended for radicular pain. Trigger point injections with a local anesthetic may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome when all of the following criteria are met: (1) Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain; (2) Symptoms have persisted for more than three months; (3) Medical management therapies such as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain; (4) Radiculopathy is not present (by exam, imaging, or neuro-testing); (5) Not more than 3-4 injections per session; (6) No repeat injections unless a greater than 50% pain relief is obtained for six weeks after an injection and there is documented evidence of functional improvement; (7) Frequency should not be at an interval less than two months; (8) Trigger point injections with any substance (e.g., saline or glucose) other than local anesthetic with or without steroid are not recommended. (Colorado, 2002) (BlueCross BlueShield, 2004). In this case, as stated above, the patient does not qualify for this treatment modality. This is secondary to lack of documentation of the first criteria which is: Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain." As such, the request is not medically necessary.

**Norco 5/325mg, #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use; Opioids for chronic pain Page(s): 79-80, 81.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 of 127.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Fenoprofen Calcium 400mg, #60 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47.

**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 (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008). Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (Van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain, this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007). Back Pain: Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006). See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009)As stated above, acetaminophen would be considered first-line

treatment for chronic pain. In this case, the use of an NSAID is not advised. This is secondary to the duration of use and significant side effect profile. Also, the use of NSAIDs is known to delay the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not medically necessary.

**Gabapentin 100mg, #60 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Specific Anti-Epilepsy Drugs - Gabapentin.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17 of 127.

**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. Their also 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 inadequate 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.

**Transcutaneous electrical nerve stimulation (TENS) patches, #4:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation); Criteria for the use of TENS Page(s): 114, 116.

**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) (Khadikar2, 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. (Khadilkar-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.

**Lidopro cream 120gm:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112 of 127.

**Decision rationale:** The request is for the use of topical lidocaine. The MTUS guidelines state the following: Lidocaine Indication: Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti- depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal

patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, as stated above, the patient does not meet the criteria for use of this product in this formulation. There is a requirement of documentation of a first-line therapy trial prior to use of a lidocaine dermal patch. There is also no other commercially approved topical formulations of lidocaine indicated for neuropathic pain other than Lidoderm. As such, the request is not medically necessary.