

Case Number:	CM15-0189625		
Date Assigned:	10/01/2015	Date of Injury:	07/13/2011
Decision Date:	12/07/2015	UR Denial Date:	09/11/2015
Priority:	Standard	Application Received:	09/25/2015

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 61 year old male, who sustained an industrial injury on 7-13-11. The injured worker is being treated for lumbar spine disc protrusion with radiculopathy and nerve encroachment, bilateral hip sprain-strain, bilateral hip trochanter bursitis, bilateral knee strain-sprain, bilateral ankle strain-sprain, bilateral Achilles tendinitis, partial of right Achilles tendon and insomnia. Treatment to date has included physical therapy (provided some relief, number of sessions completed is unclear), home exercise program, shockwave treatments (unclear how many sessions or improvement in pain or function with treatments) and activity modifications. On 7-23-15, the injured worker complains of low back pain with radiation to the bilateral buttocks, bilateral thighs, bilateral calves and bilateral feet rated 5 out of 10 and increased to 8-9 out of 10 with walking, standing, repetitive lifting and riding in a car; bilateral knee pain associated with clicking, popping and giving way and rated 5 out of 10 and increased to 8-9 out of 10 with activities; bilateral ankle pain rated 5 out of 10 and increased to 8-9 out of 10 with activities and insomnia due to pain. Work status is noted to be retired. Physical exam performed on 7-23-15 revealed tenderness to palpation over the bilateral sacroiliac joints, bilateral sciatic notches, bilateral posterior iliac crests and bilateral gluteal muscles with palpable spasm of bilateral gluteal muscles and restricted lumbar range of motion; tenderness to palpation over the anterior, poster and lateral aspects of the bilateral hips with limited bilateral range of motion; tenderness to palpation over the anterior, posterior and lateral aspects bilaterally with tenderness of the bilateral patellae, bilateral lateral femoral condyle and bilateral lateral tibial condyle and tenderness to palpation over the anterior, posterior and lateral aspects of right ankle

with normal range of motion. The treatment plan included (MRI) magnetic resonance imaging of right knee, extracorporeal shockwave therapy, LINT program, transcutaneous electrical nerve stimulation (TENS) unit and Flurbi cream and Gabacyclotram cream along with Tramadol 50mg #60 and physical therapy 3 times a week for 4 weeks. On 9-11-15 request for (MRI) magnetic resonance imaging of right knee, extracorporeal shockwave therapy, LINT program, transcutaneous electrical nerve stimulation (TENS) unit and Flurbi cream and Gabacyclotram cream along with motorized hot and cold unit and physical therapy 3 times a week for 4 weeks were non-certified by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbi (Nap) cream-LA (Flurbiprofen 20%/Lidocaine 5%/Amitriptyline 5%) 180g: 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 compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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 stated above, the patient would not qualify for the use of a topical NSAID. This is based on the diagnosis and treatment duration. As such, the request is not medically necessary.

Gabacyclotram (Gabapentin 10%/Cyclobenzaprine 6%/Tramadol 10%) 180g: 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 not indicated for use for the patient's condition. This is secondary to poor clinical evidence of efficacy. As such, the request is not medically necessary.

Motorized hot and cold unit: Upheld

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

MAXIMUS guideline: Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment.

Decision rationale: The request is for the use of hot or cold treatment to be applied topically to aid in pain relief. The ACOEM guidelines under Physical Methods states that during the acute to subacute phase of injury over the first 2 weeks, application of hot or cold can be effective in ameliorating symptoms. This would aid in facilitation of mobility and exercise. Due to the longstanding duration after injury, continued use would not be indicated in this case. As such, the request is not medically necessary.

TENS 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. (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.

Localized intense neurostimulation therapy (LINT) once a week for 6 weeks for the 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)/Hyperstimulation analgesia.

Decision rationale: The request is for Localized Intense Therapy to aid in pain relief. The MTUS guidelines are silent regarding this issue. The Official Disability Guidelines state the following: Not recommended until there are higher quality studies. Initial results are promising, but only from two low quality studies sponsored by the manufacturer ([REDACTED] , [REDACTED]). Localized manual high-intensity neurostimulation devices are applied to small surface areas to stimulate peripheral nerve endings (A / fibers), thus causing the release of endogenous endorphins. This procedure, usually described as hyperstimulation analgesia, has been investigated in several controlled studies. However, such treatments are time consuming

and cumbersome, and require previous knowledge of the localization of peripheral nerve endings responsible for LBP or manual impedance mapping of the back, and these limitations prevent their extensive utilization. The new device is capable of automatically measuring skin impedance in a selected body area and, immediately afterwards, of stimulating multiple points that are targeted according to differentiation in their electrical properties and proprietary image processing algorithms with high intensity yet non-painful electrical stimulation. The therapeutic neurostimulation pulse modulation of dense electrical pulses is applied locally to specific Active Trigger Points (ATPs) which are locations of nerve ending associated with pain, providing effective pain relief by stimulating the release of endorphins, the body's natural pain killers. The gate control theory of pain describes the modulation of sensory nerve impulses by inhibitory mechanisms in the central nervous system. One of the oldest methods of pain relief is generalized hyperstimulation analgesia produced by stimulating myofascial trigger points by dry needling, acupuncture, intense cold, intense heat, or chemical irritation of the skin. The moderate-to-intense sensory input of hyperstimulation analgesia is applied to sites over, or sometimes distant from, the pain. A brief painful stimulus may relieve chronic pain for long periods, sometimes permanently. The new device takes advantage of these same principles. Hyperstimulation analgesia with localized, intense, low-rate electrical pulses applied to painful active myofascial trigger points was found to be effective in 95% patients with chronic nonspecific low back pain, in a clinical validation study. (Gorenberg, 2013) The results of this current pilot study show that treatment with this novel device produced a clinically significant reduction in back pain in almost all patients after four treatment sessions. (Gorenberg, 2011) As stated above, this treatment is not indicated. This is secondary to poor high quality clinical evidence of effectiveness. As such, the request is not medically necessary.

Extracorporeal shockwave therapy (ECSWT) once a week for 4 weeks for the right hip:
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) Knee & Leg.

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.

MRI scan of the right knee: 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) Knee & Leg (Acute & Chronic)/MRIs (magnetic resonance imaging).

Decision rationale: The request is for an MRI of the knee. The Official Disability Guidelines state the following regarding this topic: Indications for imaging -- MRI (magnetic resonance imaging):- Acute trauma to the knee, including significant trauma (e.g, motor vehicle accident), or if suspect posterior knee dislocation or ligament or cartilage disruption.- Non-traumatic knee pain, child or adolescent: non-patellofemoral symptoms. Initial anteroposterior and lateral radiographs non-diagnostic (demonstrate normal findings or a joint effusion) next study if clinically indicated. If additional study is needed.- Non-traumatic knee pain, child or adult. Patellofemoral (anterior) symptoms. Initial anteroposterior, lateral, and axial radiographs non-diagnostic (demonstrate normal findings or a joint effusion). If additional imaging is necessary, and if internal derangement is suspected. Non-traumatic knee pain, adult. Non-trauma, non-tumor, non-localized pain. Initial anteroposterior and lateral radiographs non-diagnostic (demonstrate normal findings or a joint effusion). If additional studies are indicated, and if internal derangement is suspected. Non-traumatic knee pain, adult - non-trauma, non-tumor, non-localized pain. Initial anteroposterior and lateral radiographs demonstrate evidence of internal derangement (e.g., Peligrini Stieda disease, joint compartment widening). Repeat MRIs: Post-surgical if need to assess knee cartilage repair tissue. (Ramappa, 2007) Routine use of MRI for follow-up of asymptomatic patients following knee arthroplasty is not recommended. (Weissman, 2011) In this case, the study is not indicated. This is secondary to poor documentation of qualifying factors as listed above. As such, the request is not medically necessary.