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| Case Number: | CM15-0175178 | | |
| Date Assigned: | 10/16/2015 | Date of Injury: | 05/30/2015 |
| Decision Date: | 12/24/2015 | UR Denial Date: | 08/11/2015 |
| Priority: | Standard | Application Received: | 09/04/2015 |

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 40 year old, female who sustained a work related injury on 5-30-15. A review of the medical records shows she is being treated for low back pain. In the progress notes dated 7-29-15, the injured worker reports occasional, shooting lower back pain with radiating pain to her left hip and leg. She has numbness and tingling in her left leg. She has frequent, dull left leg pain that radiates down left leg to hip and ankle. On physical exam dated 7-29-15, she has tenderness along the lumbar paravertebral muscles and left sacroiliac joint. She has spasm along the left quadratus lumborum muscles and left gluteus. She has a positive left leg raise. Treatments have included-none. Current medications include-none listed. She is not working. The treatment plan includes requests for a functional capacity evaluation, for x-rays of the lumbar spine, for Naproxen, for a trial course of TENS unit therapy, and chiropractic therapy. In the Utilization Review dated 8-11-15, the requested treatments of x-rays of the lumbar spine, 1 month trial of TENS unit therapy, a urine drug screen, Flurbiprofen-menthol-capsaicin-camphor cream, a functional capacity evaluation, and chiropractic treatments x 12 sessions are all not medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

X-rays of lumbar spine: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Chapter: P Radiography (X-rays).

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/x-rays.

Decision rationale: The request is for x-rays of the low back. The ODG state the following regarding qualifying criteria: Not recommend routine x-rays in the absence of red flags. (See indications list below.) Indications for imaging, Plain X-rays: Thoracic spine trauma: severe trauma, pain, no neurological deficit; Thoracic spine trauma: with neurological deficit; Lumbar spine trauma (a serious bodily injury): pain, tenderness; Lumbar spine trauma: trauma, neurological deficit; Lumbar spine trauma: seat belt (chance) fracture; Uncomplicated low back pain, trauma, steroids, osteoporosis, over 70; Uncomplicated low back pain, suspicion of cancer, infection; Myelopathy (neurological deficit related to the spinal cord), traumatic; Myelopathy, painful; Myelopathy, sudden onset; Myelopathy, infectious disease patient; Myelopathy, oncology patient; Post-surgery: evaluate status of fusion. In this case, there is inadequate documentation of red flags which would warrant x-rays. There are no physical exam findings of a change in neurologic status or a new deficit. Pending this information, the request is not medically necessary.

Functional capacity evaluation - lumbar and/or sacral vertebrae: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM chapter 7; Independent Medical Examinations and Consultations, pgs 132-139 and Official Disability Guidelines (ODG), Fitness for Duty chapter: FCE.

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 that it is 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. 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.

Compounded medication: Flurbi-Menthol-Caps-Camph cream #1 tube: 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 treatment duration with the patient's injury being far greater than 12 weeks. As such, the request is not medically necessary.

Urine drug screen: 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. The frequency of drug testing is indicated below: Patients at low risk of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Patients at moderate risk for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, those patients in unstable and/or dysfunction social situations, and for those patients with comorbid psychiatric pathology. Patients at high risk of adverse outcomes may require testing as often as once per month. This category generally includes individuals with active substance abuse disorders. 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.

TENS unit (one month trial): 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) (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. (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 acute low back pain is not indicated. There is also poor evidence of utility in chronic low back pain as well, with the Centers of Medicare & Medicaid Services stating 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." As such, the request is not medically necessary.

Chiropractic therapy x12, 3 times a week for 4 weeks, for the lumbar and/or sacral vertebrae: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004, and 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)/Manipulation.

Decision rationale: The request is for chiropractic treatment. The official disability guidelines state the following regarding this matter: Therapeutic care: Mild: up to 6 visits over 2 weeks. - Severe: Trial of 6 visits over 2 weeks. (Severe may include severe sprains/strains (Grade II-III1) and/or non-progressive radiculopathy (the ODG Chiropractic Guidelines are the same for sprains and disc disorders)) Severe: With evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks, if acute, avoid chronicity. Elective/maintenance care: Not medically necessary. Recurrences/flare-ups: Need to re-evaluate treatment success, if RTW achieved then 1-2 visits every 4-6 months when there is evidence of significant functional limitations on exam that are likely to respond to repeat chiropractic care. In this case, further treatment is not guideline-supported. This is secondary to an excess number of sessions requested. An initial trial of 6 visits over 2 weeks is advised, and with evidence of objective functional improvement additional therapy can be performed. As such, the request is not medically necessary.