

Case Number:	CM15-0072701		
Date Assigned:	05/19/2015	Date of Injury:	10/06/2011
Decision Date:	09/22/2015	UR Denial Date:	03/27/2015
Priority:	Standard	Application Received:	04/16/2015

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 46 year old male who sustained an industrial injury on 10/06/2011. Mechanism of injury was a fall down steps while working. Diagnoses include discogenic lumbar condition with facet inflammation and left-sided radiculopathy, and status post-surgery with persistent symptomology. Treatment to date has included diagnostic studies, medications, status post left L5 and S1 laminotomy, discectomy, foraminotomy and decompression of L5 and S1 nerve roots on 01/13/2014, chiropractic sessions, back brace, and injections. A physician progress note dated 03/03/2015 documents the injured worker complains of low back pain which he rates as 4-7 on a pain scale of 0-10. The pain radiates down to the left calf. He is also having numbness, tingling, cramping and waking up because of pain, tension and spasms. He has associated symptoms of depression, sexual dysfunction, difficulty falling asleep, and loss of concentration. On examination of the back and lower extremities he refuses to squat and lumbar flexion due to pain, and extension is no more than 10 degrees. Dorsiflexion is less than 10 degrees and plantar flexion is less than 20 degrees with less than full effort provided. Straight leg raise no more than 30 degrees on the right and 60 degrees on the left with discomfort with the injured worker grimacing and wincing. He has tenderness across the lumbar paraspinal muscles, pain along the facets, and pain with facet loading at L3-S1. The treatment plan includes a new Magnetic Resonance Imaging of the lumbar spine to evaluate for post-surgical changes, psychiatry for possible injections, spine consultation, electromyography of lower extremities, a low back brace, and medications. Treatment requested is for 1 TENS conductive garment, 1

TENS unit, 1 hot and cold wrap, 12 chiropractic sessions, 12 physical therapy sessions, and Protonix 20mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nalfon 400mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-68 of 127.

Decision rationale: The request is for the use of NSAIDS to aid in pain relief. NSAIDS are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIS are 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, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDS appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDS and COX-2 NSAIDS in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDS having fewer GI side effects at the risk of increased cardiovascular side effects. 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 and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDS are recommended as a second-line treatment after acetaminophen. In general, there is conflicting 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) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

Protonix 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms & Cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68 of 127.

Decision rationale: The request is for the use of a medication in the class of a proton pump inhibitor. This is usually given as an acid reducing medication 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. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. 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.

12 chiropractic sessions: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy and manipulation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58-60 of 127.

Decision rationale: The request is for chiropractic treatment to aid in pain relief. The MTUS guidelines states that manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. It is indicated for low back pain but not ankle and foot conditions, carpal tunnel syndrome, forearm/wrist/hand pain, or knee pain. The use of active treatment modalities instead of passive treatments is associated with substantially better clinical outcomes. (Fritz, 2007) Active treatments also allow for fading of treatment frequency along with active self-directed home PT, so that less visits would be required in uncomplicated cases. In this case, the patient would benefit most from at home active therapy. As such, the request is not medically necessary.

12 physical therapy sessions: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58-60 of 127.

Decision rationale: The request is for physical therapy to aid in pain relief. The MTUS guidelines states that manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. It is indicated for low back pain but not ankle and foot conditions, carpal tunnel syndrome, forearm/wrist/hand pain, or knee pain. The use of active treatment modalities instead of passive treatments is associated with substantially better clinical outcomes. (Fritz, 2007) Active treatments also allow for fading of treatment frequency along with active self-directed home PT, so that less visits would be required in uncomplicated cases. In this case, the patient would benefit most from at home active therapy. As such, the request is not medically necessary.

1 hot and cold wrap: 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: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 48.

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.

1 TENS unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

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, 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 low back pain is not indicated. There is a lack of quality evidence for its effectiveness. As such, the request is not medically necessary.

1 TENS conductive garment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

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).

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