

Case Number:	CM15-0187822		
Date Assigned:	10/21/2015	Date of Injury:	10/06/2011
Decision Date:	12/29/2015	UR Denial Date:	09/09/2015
Priority:	Standard	Application Received:	09/24/2015

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: Physical Medicine & Rehabilitation, Pain Management

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 47 year old male who sustained an industrial injury on 10-6-11. A review of the medical records indicates he is undergoing treatment for discogenic lumbar condition and chronic pain and inactivity with weight loss, sleep issues, and sexual dysfunction. Medical records (7-21-15, 8-21-15) indicate ongoing complaints of low back pain with numbness, tingling, and cramping. The physical exam (8-21-15) reveals "dorsiflexion" less than 10 degrees and "palmar flexion no more than 20 degrees". The straight leg raise is positive at 30 degrees on the right and 60 degrees on the left. Facet loading is positive from L3-S1. Tenderness is noted along the paraspinal musculature. Diagnostic studies have included an MRI of the lumbar spine and nerve conduction studies. Treatment has included physical therapy, chiropractic treatment, a back brace, use of a hot and cold wrap, and medications. A request for authorization for Effexor XR, Norco, Ultracet, Lunesta, Topamax, Voltaren XR, Protonix, and Norflex, as well as a 4-lead TENS unit with conductive garment and a urine drug screen was made. The injured worker was receiving Tramadol ER since, at least 4-24-13. He was not noted to be receiving Lunesta or Norflex prior to the 8-21-15 record. The utilization review (9-9-15) includes a request for authorization of Lunesta 2mg #30, Ultracet 37.5mg #60, Norflex ER 100mg #60, a 4-lead TENS unit with conductive garment, and a 10-panel drug screen. All requests were denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lunesta 2mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic), Eszopiclone (Lunesta), Insomnia Treatment.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter & Mental Illness and Stress Chapter, Insomnia Topics.

Decision rationale: Regarding the request for Lunesta, California MTUS guidelines are silent regarding the use of sedative hypnotic agents. ODG recommends the short-term use (usually two to six weeks) of pharmacological agents only after careful evaluation of potential causes of sleep disturbance. With Eszopiclone (Lunesta), the guidelines state this agent "has demonstrated reduced sleep latency and sleep maintenance." It is the only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. Within the documentation available for review, there is no statement indicating what behavioral treatments have been attempted for the condition of insomnia. The ODG recommends non-pharmacologic treatments and education on behavior techniques and sleep hygiene as first line. Given this, the current request is not medically necessary.

Ultracet 37.5mg #60: 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): Opioids, criteria for use, Opioids for chronic pain, Opioids, specific drug list.

Decision rationale: Tramadol is a centrally acting opioid agonist and also inhibits the reuptake of serotonin and norepinephrine. On July 2, 2014, the DEA published in the Federal Register the final rule placing tramadol into schedule IV of the Controlled Substances Act. This rule became effective on August 18, 2014. The CPMTG specifies that this is a second line agent for neuropathic pain. Given its opioid agonist activity, it is subject to the opioid criteria specified on pages 76-80 of the CPMTG. With regard to this request, the California Chronic Pain Medical Treatment Guidelines state the following about on-going management with opioids: "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the '4 A's' (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). 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." Guidelines further recommend discontinuing opioids if there is no documentation of improvement in function and reduction in pain. In the progress reports available for review, the

requesting provider did not adequately document monitoring of the four domains. Improvement in function was not clearly outlined. This can include a reduction in work restrictions or significant gain in some aspect of the patient's activities. Based on the lack of documentation, medical necessity of this request cannot be established at this time. Although tramadol is not medically necessary at this time, it should not be abruptly halted, and the requesting provider should start a weaning schedule as he or she sees fit or supplies the requisite monitoring documentation to continue this medication.

Norflex ER 100mg #60: 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): Muscle relaxants (for pain).

Decision rationale: With regard to the request for orphenadrine, Chronic Pain Medical Treatment Guidelines state that non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Specifically regarding Norflex (Orphenadrine), the guidelines state: "This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects." In the submitted medical records available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the muscle relaxants. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. In the absence of such documentation, the currently requested orphenadrine is not medically necessary.

Four Lead TENS Unit with Conductive Garment: 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): Transcutaneous electrotherapy.

Decision rationale: Regarding the request for TENS, the Chronic Pain Medical Treatment Guidelines on Pages 114-116 specify the following regarding TENS (transcutaneous electrical nerve stimulation): Not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide

information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. (Carroll-Cochrane, 2001) Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. One problem with current studies is that many only evaluated single-dose treatment, which may not reflect the use of this modality in a clinical setting. Other problems include statistical methodology, small sample size, influence of placebo effect, and difficulty comparing the different outcomes that were measured. Recommendations by types of pain: A home-based treatment trial of one month may be appropriate for neuropathic pain and CRPS II (conditions that have limited published evidence for the use of TENS as noted below), and for CRPS I (with basically no literature to support use). 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) A review of this injured worker's industrial diagnoses failed to reveal any of the indications above of multiple sclerosis, spasticity, phantom limb pain, or complex regional pain syndrome as described by the CPMTG. By statute, the California Medical Treatment and Utilization Schedule takes precedence over other national guidelines which may have broader indications for TENS unit.

Given this worker's diagnoses, TENS is not medically necessary.

10-Panel Urine Drug Screen: 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): Drug testing, Opioids, criteria for use, Opioids, dealing with misuse & addiction.

Decision rationale: Regarding the request for a urine toxicology test, CA MTUS Chronic Pain Medical Treatment Guidelines state the drug testing is recommended as an option in patients on controlled substances. Guidelines go on to recommend monitoring for the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. ODG recommends urine drug testing on a yearly basis for low risk patients, 2-3 times a year for moderate risk patients, and possibly once per month for high risk patients. Risk stratification is an important component in assessing the necessity and frequency of urine drug testing. With the documentation available for review, there is documentation of prescription of controlled substances. However, there is no notation of when the last previous urine toxicology testing was done. No risk factor assessment, such as the utilization of the Opioid Risk Tool or SOAPP is apparent in the records, which would dictate the schedule of random periodic drug testing. Given this, this request is not medically necessary, it should be noted that if this information is supplied, the urine toxicology test may become medically necessary at same time in the future.