

Case Number:	CM15-0188269		
Date Assigned:	09/30/2015	Date of Injury:	09/21/2009
Decision Date:	11/09/2015	UR Denial Date:	09/02/2015
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: Tennessee, Florida, Ohio
 Certification(s)/Specialty: Surgery, Surgical Critical Care

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 41 year old male with an industrial injury dated 09-21-2009. A review of the medical records indicates that the injured worker is undergoing treatment for lumbago and thoracic or lumbosacral neuritis or radiculitis. Treatment has included diagnostic studies, prescribed medications, and periodic follow up visits. Medical records (04-28-2015) indicate ongoing head pain, back pain, bilateral leg pain and bilateral feet pain. In a progress report dated 07-28-2015, the injured worker reported same symptoms of back pain and numbness below his waist. The injured worker reported his back pain increased as he had a severe jolt of back pain that resulted in fall on street and emergency visit. Objective findings (07-28-2015) revealed moderate severe depression symptoms and non-antalgic gait. According to the progress note dated 08-26-2015, the injured worker reported continued daily severe "aching and sharp, jolting" type pain in the bilateral low back with generalized numbness and tingling of the bilateral legs and entire feet and toes. The injured worker reported that his leg "gives out" after 15 minutes of prolonged walking and he falls to the ground. The injured worker reported migraine headaches and neck tightness. The injured worker continues with daily Norco and MS Contin uses and reported 50% reduction in pain and that he is able to perform light household chores and self-care with pain medication. The injured worker also uses Gabapentin, Flexeril, Lidoderm 5% patches which he reported are helpful and he uses Zofran for intermittent nausea and vomiting. The injured worker rated current pain 8 out of 10 and interval pain over past week an 8 out of 10. The injured worker related pain relief with medication or treatment over the last week at 50%. Objective findings (08-26-2015) revealed moderate depression symptoms, minimal range of

motion in all fields with end range pain, decreased sensation to light touch, tenderness with minimal touch of lumbar paraspinal area bilaterally and non-antalgic gait. The treatment plan medication management, acupuncture therapy, psychological evaluation, spinal cord stimulator trial, consultation and follow up visit. Medical records indicate that the injured worker has been on Cyclobenzaprine since 04-04-2012, Gabapentin since at least 08-22-2013, and Zofran since 12-04-2014. The urine drug screen performed on 07-28-2015 was positive for opiates and oxycodone. The treating physician requested Cyclobenzaprine 10 mg Qty 90, Lidocaine 5% external patch Qty 30, Zofran ODT 8 mg, Gabapentin 300 mg Qty 90, spinal cord stimulator, trial, spinal cord stimulator, permanent (upon successful trial) and follow up visit. The original utilization review determination (09-02-2015) non-certified the request for Cyclobenzaprine 10 mg Qty 90, Lidocaine 5% external patch Qty 30, Zofran ODT 8 mg, Gabapentin 300 mg Qty 90, spinal cord stimulator, trial, spinal cord stimulator, permanent (upon successful trial) and follow up visit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 10 mg Qty 90: 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: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. In accordance with the California MTUS guidelines, Cyclobenzaprine is a muscle relaxant and muscle relaxants are not recommended for the treatment of chronic pain. From the MTUS guidelines: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic back pain. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence." This patient has been diagnosed with chronic back pain of the thoracic and lumbar spine. Per MTUS, the chronic use of a muscle relaxant is not indicated. Therefore, based on the submitted medical documentation, the request for Cyclobenzaprine is not-medically necessary.

Lidocaine 5% external patch Qty 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Lidoderm.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Lidoderm patch prescription. In accordance with California Chronic Pain MTUS

guidelines, Lidoderm (topical Lidocaine) may be recommended for localized peripheral pain after there has been a trial of a first-line treatment. The MTUS guideline specifies "tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica" as first line treatments. The provided documentation does not show that this patient was tried and failed these recommended first line treatments. Topical Lidoderm is not considered a first line treatment and is currently only FDA approved for the treatment of post-herpetic neuralgia. Therefore, based on the submitted medical documentation, the request for Lidoderm patch prescription is not medically necessary.

Zofran ODT 8 mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA (Food & Drug Administration) - Ondanestron.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zofran FDA Prescribing Guidelines <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm271924.htm>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address this topic. According to its FDA prescribing recommendations, "Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery." It is in a class of medications called 5-HT3 receptor antagonists and works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting. This patient has chronic back pain which is currently being treated with opioids. He had not undergone surgery or been diagnosed with the need for chemotherapy/radiation. Thus, the requested medication is being prescribed against FDA indications. Therefore, based on the submitted medical documentation, the request for Ondansetron is not-medically necessary.

Gabapentin 300 mg Qty 90: 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): Antiepilepsy drugs (AEDs).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. MTUS Chronic Pain Guidelines note Gabapentin is an anti-epilepsy drug (AEDs-also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The Guidelines recommend Gabapentin for patients with spinal cord injury as a trial for chronic neuropathic pain that is associated with

this condition. The Guidelines also recommend a trial of Gabapentin for patients with fibromyalgia and patients with lumbar spinal stenosis. Within the provided documentation it did not appear the patient had a diagnosis of diabetic painful neuropathy or postherpetic neuralgia to demonstrate the patient's need for the medication at this time. Additionally, the requesting physician did not include adequate documentation of objective functional improvements with the medication or decreased pain from use of the medication in order to demonstrate the efficacy of the medication. Therefore, based on the submitted medical documentation, the request for Neurontin is not medically necessary.

Spinal Cord Stimulator, trial: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Spinal cord stimulators (SCS).

Decision rationale: Recommended as indicated below. Spinal cord stimulators (SCS) should be offered only after careful counseling and patient identification and should be used in conjunction with comprehensive multidisciplinary medical management. Indications for stimulator implantation: Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation), more helpful for lower extremity than low back pain, although both stand to benefit, 40-60% success rate 5 years after surgery. It works best for neuropathic pain. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar. Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.)- Post amputation pain (phantom limb pain), 68% success rate Post herpetic neuralgia, 90% success rate, Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury), Pain associated with multiple sclerosis, Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina. Per the California MTUS Guidelines for Chronic Pain, this patient does not meet criteria for implantation of a spinal cord stimulator. Specifically, this patient has been diagnosed with chronic back pain. The patient has not undergone any surgical intervention on the spine and there is not documentation in the medical record that the patient is not a surgical candidate. Hence, implantation and trial of the device is not indicated based on the presently submitted medical documentation. Therefore, based on the submitted medical documentation, the request for spinal cord stimulator trial is not medically necessary.

Spinal Cord Stimulator, permanent (upon successful trial): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Spinal Cord Stimulator.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Spinal cord stimulators (SCS).

Decision rationale: Recommended as indicated below. Spinal cord stimulators (SCS) should be offered only after careful counseling and patient identification and should be used in conjunction with comprehensive multidisciplinary medical management. Indications for stimulator implantation: Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation), more helpful for lower extremity than low back pain, although both stand to benefit, 40-60% success rate 5 years after surgery. It works best for neuropathic pain. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar.- Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.)- Post amputation pain (phantom limb pain), 68% success rate Post herpetic neuralgia, 90% success rate, Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury), Pain associated with multiple sclerosis, Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina. Per the California MTUS Guidelines for Chronic Pain, this patient does not meet criteria for implantation of a spinal cord stimulator. Specifically, this patient has been diagnosed with chronic back pain. The patient has not undergone any surgical intervention on the spine and there is not documentation in the medical record that the patient is not a surgical candidate. Hence, implantation and trial of the device is not indicated based on the presently submitted medical documentation. Therefore, based on the submitted medical documentation, the request for implantation of a permanent spinal cord stimulator upon successful completion of a trial is not medically necessary.

Follow up visit: 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 - Evaluation & Management (E&M), office visits.

MAXIMUS guideline: Decision based on MTUS Stress-Related Conditions 2004, Section(s): Follow-up.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a follow-up visit for this patient. The California MTUS guidelines state: "Frequency of follow-up visits may be determined by the severity of symptoms, whether the patient was referred for further testing and/or psychotherapy, and whether the patient is missing work. These visits allow the physician and patient to reassess all aspects of the stress model (symptoms, demands, coping mechanisms, and other resources) and to reinforce the patient's supports and positive coping mechanisms." Additionally, "Follow-up by a physician can occur when a change in duty status is anticipated (modified, increased, or full duty) or at least once a week if the patient is missing work." This patient has chronic back pain that has been evaluated by a thoracic spine specialist. The patient has been documented to have failed multiple medical treatments and continues to have limited range of motion with objective evidence of impairment. However, there is no documentation of goals of therapy or plans for the patient's planned follow-up visit. Therefore, based on the submitted medical documentation, the request for follow-up visit is not-medically necessary.

