

Case Number:	CM15-0125038		
Date Assigned:	07/09/2015	Date of Injury:	12/06/2002
Decision Date:	09/21/2015	UR Denial Date:	06/17/2015
Priority:	Standard	Application Received:	06/29/2015

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: New York

Certification(s)/Specialty: Internal 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 53 year old male, who sustained an industrial injury on 12/06/2002. According to a progress report dated 04/06/2015, the injured worker was currently working and going to school. He had neck pain, pain in both shoulders, left elbow, low back and history of an abdominal hernia. His pain would come and go. He had worse pain with activity and with cold weather. He had difficulty sleeping and took Trazodone for sleep and Mirtazapine for depression. He took medications for hypertension. Objective findings included tenderness across the lumbar paraspinal muscles bilaterally. Diagnoses included impingement syndrome of the shoulder on the left with instability, status post stabilization of the distal clavicle with subsequent removal of the hardware, re-stabilization and arthroscopic decompression (total 3 surgeries), impingement syndrome on the shoulder on the right side status post decompression, second surgery distal clavicle excision, bicipital tendinitis presently, discogenic cervical condition with radicular component on the upper extremities, discogenic lumbar condition involving in the past L4-L5 and L5-S1, most recent MRI showing disc disease at L4-L5 with anterolisthesis of the L4 and L5 with facet inflammation status post epidural injection with persistent symptomatology, cubital tunnel syndrome on the left status post transposition, hernia condition status post three surgical interventions with most recent in 2014, issues with headaches, depression, erectile dysfunction and weight loss of 15 pounds. The treatment plan included Trazodone for insomnia and Mirtazapine for depression, Nalfon for inflammation and Norflex for muscle spasms. The injured worker was to continue working as tolerated. According to a progress report dated 06/01/2015, the provider noted that the injured worker was going to school and was physically

able to do so at this point. He had access to a four-lead TENS unit, but did not have a conductive garment. He was minimizing chores. He had an element of depression, sexual dysfunction, sleep disorder, gastrointestinal irritation and headaches. He was not doing any chores around the house. Objective findings included blood pressure of 125/67 and pulse 58. Abduction of the arm was 120 degrees. Tenderness along the biceps tendon on the right side was noted with significance. He had a positive speed test and mild findings of impingement. Tenderness along the acromioclavicular joint was not noted. On the left, tenderness along the acromioclavicular joint was not noted either where he had a distal clavicle excision. The provider noted that based on the pain in the neck traveling down the left arm and shoulder, a referral to physiatry was recommended. The provider noted that the injured worker would get a 10 panel urine screen. He was to continue working, avoiding forceful pushing and pulling, overhead activities, prolonged sitting and standing and forceful gripping, grasping and torquing. Authorization was going to be requested for nerve studies of the upper extremity, conductive garment and elbow pad, referral for psychiatry consultation and physiatry consultation, Nalfon, Aciphex, Trazodone, Remeron, Effexor, Norflex ER, Topamax, and Maxalt and MRI of shoulder subacromial injection, possible biceps injection on the right shoulder (once the right shoulder is rectified for coverage). An authorization request dated 06/01/2015 was submitted for review. The requested services included electromyography/nerve conduction velocity studies of the bilateral upper extremities, durable medical equipment stimulators/conductive garment, elbow pad, referral to physiatry and Nalfon, Aciphex, Trazodone, Remeron, Effexor, Norflex, Topamax and Maxalt. Currently under review is the request for Aciphex 20 mg #30, Topamax 50 mg #60 Maxalt 10 mg #24, 10-panel urine screen and conductive garment.

IMR ISSUES, DECISIONS AND RATIONALES

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

AcipHex 20mg #30: 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 NSAIDS, gastrointestinal symptoms & cardiovascular risks Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Proton Pump Inhibitors.

Decision rationale: According to the CA MTUS, proton pump inhibitors, such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. Official Disability Guidelines (ODG) states that proton pump inhibitors are recommended for patients at risk for gastrointestinal events. Decision to use proton pump inhibitors long-term must be weighed against the risks. The potential adverse effects of long-term proton pump inhibitor use included B12 deficiency, iron deficiency, hypomagnesemia, increased susceptibility to pneumonia, enteric infection and fractures, hypergastrinemia and cancer and more recently adverse cardiovascular effects. Proton pump inhibitors have a negative effect on vascular function, increasing the risk for myocardial infarction. Patients with

gastroesophageal reflux disease on proton pump inhibitors had a 1.16 greater risk of myocardial infarction and a 2.00 risk for cardiovascular mortality. Proton pump usage may be serving as a marker for a sicker population, but this is unlikely, given the lack of increased risk seen in patients taking H2 blockers. (Shah, 2015) In this study proton pump inhibitor use was associated with a 1.58 fold greater risk of myocardial infarction and in the case-crossover study, adjusted odds ratios of proton pump inhibitor for myocardial risk were 4.61 for the 7 day window and 3.47 for the 14 day window. However, the benefits of proton pump inhibitors may greatly outweigh the risks of adverse cardiovascular effects, with number needed to harm of 4357. (Shih, 2014) Outpatient proton pump use is associated with a 1.5 fold increased risk of community-acquired pneumonia, with the highest risk within the first 30 days after initiation of therapy. (Lamber, 2015) The updated Beers Criteria, which help prevent adverse drug events in older adults, added a recommendation to avoid the use of proton pump inhibitors for more than 8 weeks, except for long-term NSAID users and patients with erosive esophagitis, Barrett's esophagitis, pathologic hypersecretory condition, or a demonstrated need for maintenance therapy. There are many studies demonstrating, in elderly patients, an increased risk for Clostridium difficile infection and bones loss and fractures with the long-term use of proton pump inhibitors. (AGS, 2015) ODG Guidelines state that Aciphex should be second-line. In this case there is no documentation indicating the patient has any GI risk factors. However, gastrointestinal irritation was noted. Guidelines recommend Aciphex as second-line treatment. There was no documentation indicating that treatment with first line proton pump inhibitors had failed. The medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.

Topamax 50mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topiramate (Topamax).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management/Anti-epilepsy drugs/Topiramate (Topamax) Page(s): 9, 16-17, 21.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines state that all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. CA MTUS Chronic Pain Medical Treatment Guidelines recommend anti-epilepsy drugs for neuropathic pain (pain due to nerve damage). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials for the use of this class of medications for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: a switch to a different first-line agent (tricyclic antidepressant, serotonin norepinephrine reuptake inhibitor or antiepileptic drug are considered first line treatment) or combination therapy if treatment with a

single drug agent fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of antiepileptic drugs depends on improved outcomes versus tolerability of adverse effects. MTUS guidelines state Topiramate (Topamax) state Topiramate (Topamax) has been shown to have variable efficacy with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard. In this case, there is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. There was no documentation of a 30-50% reduction of pain with use of Topamax. The medical necessity for the request treatment is not established. The requested treatment is not medically necessary.

Maxant 10mg #24: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Head, Rizatriptan (Maxalt).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head Chapter/Triptans.

Decision rationale: Rizatriptan (Maxalt) is a 5-HT₁ receptor agonist of the triptan class. It is recommended for migraine sufferers. At marketed doses, all oral triptans are effective and well tolerated. In this case, the injured worker was noted to have issues with headaches. There is no specific documentation regarding the relief the injured worker has from the use of this medication. Medical necessity for the requested medication has not been established. The request for Maxalt 10mg #24 is not medically necessary.

10-panel urine screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Steps to avoid misuse of opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing, Ongoing Management of Opioids Page(s): 43, 78. Decision based on Non-MTUS Citation Pain Chapter/Urine Drug Testing.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines state drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs. Guidelines recommend use of drug screening or inpatient treatment with issues of abuse, addiction or poor pain control. Official Disability Guidelines state that urine drug testing 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 setting (i.e. when opioids are required for nociceptive pain). It is recommended in cases in which the patient asks for a specific drug, particularly if the drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic substitution. UDT is recommended if the patient has a positive or "at risk" addiction screen on evaluation and if aberrant behavior or misuse is suspected and/or detected. For ongoing-monitoring UDT is recommended 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. If dose increases are not decreasing pain and increasing function, consideration of urine drug testing should be made to aid in evaluating medication compliance and adherence. In this case, there is no indication for the requested treatment. The medical necessity for the requested treatment was not established. The requested treatment is not medically necessary.

Conductive garment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Form-fitting TENS device, TENS, chronic pain (transcutaneous electrical nerve stimulation).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS (transcutaneous electrical nerve stimulation), Chronic Pain Page(s): 114.

Decision rationale: MTUS guidelines state transcutaneous electrical nerve stimulation (TENS) is 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 evidenced-based functional restoration. In this case, the request was for a conductive garment to be used with transcutaneous electrical stimulation. Records fail to indicate that the injured worker was using TENS as an adjunct to a program of evidence-based functional restoration. The medical necessity of the requested treatment is not established. The request for Conductive garment is not medically necessary.