MAXIMUS Federal Services

Case Number:	CM15-0235807		
Date Assigned:	12/11/2015	Date of Injury:	03/20/2014
Decision Date:	01/20/2016	UR Denial Date:	11/30/2015
Priority:	Standard	Application Received:	12/02/2015

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: 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 48-year-old male who sustained an industrial injury on 3-20-2014 and has been treated for L4-5 protrusion with bilateral L5 neural encroachment, and lumboparaspinal trigger points. On 10-28-2015 the injured worker reported low back pain, worse on the right, with low extremity symptoms, refractory trigger points in the lumboparaspinal area leading to "significant decline" in activity and function. Significant objective findings include lumbar spine tenderness, multiple trigger points in the lumbar areas, positive straight leg raise on the right to 35 degrees and the left 40. Documented treatment includes trigger point injections, physical therapy, home exercise, activity modification, and medication including Tramadol, Hydrocodone, and Naproxen stated to help maintain activities of daily living including household duties, grooming, shopping and cooking. The injured worker is noted to report a decrease in Hydrocodone intake from as much as 5 doses, to use for breakthrough pain only since starting Tramadol. Tramadol is noted to decrease pain 4-5 points on a pain scale with 10 being the most severe, and provide "objective" improvement including greater range of motion and exercise tolerance. Hydrocodone and Tramadol are noted in the medical record for at least one year. A recent urine toxicology screen is reported as "consistent." The treating physician's plan of care includes 5 treatments of extracorporeal shockwave therapy to treat lumbo-paraspinal trigger points and myofascial pain syndrome; Hydrocodone 10-325 mg #30 stated for "weaning"; and, a retrospective request for Tramadol 150 mg #30 dispensed 10-28-2015, also stated for "weaning." All were non-certified on 11-30-2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Extracorporeal Shock Wave Therapy to Treat Lumbo-Paraspinal Trigger Points/Myofascial Pain Syndrome x 5 Sessions: 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).

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 and Thoracic: Acute & Chronic: Shock Wave Therapy.

Decision rationale: Based on ODG guidelines, shock wave therapy is not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. Therefore based on ODG guidelines and the information in this case, the request for Extracorporeal shock wave therapy to treat lumbo-paraspinal trigger points/ myofascial pain syndrome x 5 sessions is not medically necessary.

Hydrocodone 10/325 MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

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 and Thoracic: Opioids.

Decision rationale: Based on ODG guidelines, the use of opioids is not recommended except for short use for severe cases, not to exceed 2 weeks. See the Pain Chapter for more information and studies. When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. The studies found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems. (Bigos, 1999) Recent studies document a 423% increase in expenditures for opioids for back pain, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) With opioid therapy for nonspecific low back pain compared with no opioids, the odds of chronic work loss were six times greater for claimants with schedule II ("strong") opioids; were 11-14 times greater for claimants with opioid prescriptions of any type during a period of >or=90 days; and 3 years after injury, costs of claimants with schedule II

opioids averaged [redacted] higher than costs of claimants in the no opioids group. (Volinn, 2009) This large study found that prescription of opioids was common among patients with back pain, and increasing duration of opioid use was strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse); almost 50% of patients receiving long-term opioids had at least one of these diagnoses. Similarly, negative health habits (obesity, smoking) were associated with duration of opioid use. The wisdom of long-acting opioid use for chronic pain remains controversial. In this case, the patient has been on opiates for at least several months and there is documentation of improved function with ADLs and decreased pain. However, they are not recommended for long term use. A recent approval of a modified amount of medication was noted for weaning purposes. Therefore, based on ODG guidelines and the information in this case, the request for Hydrocodone 10/325 mg #60 is not medically necessary.

Retro Tramadol 150 MG #60 Dispensed on 10/28/15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

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 and Thoracic: Opioids, Pain (Chronic): tramadol.

Decision rationale: Based on ODG guidelines, the use of opioids is not recommended except for short use for severe cases, not to exceed 2 weeks. See the Pain Chapter for more information and studies. When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. The studies found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems. (Bigos, 1999) Recent studies document a 423% increase in expenditures for opioids for back pain, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) With opioid therapy for nonspecific low back pain compared with no opioids, the odds of chronic work loss were six times greater for claimants with schedule II ("strong") opioids; were 11-14 times greater for claimants with opioid prescriptions of any type during a period of >or=90 days; and 3 years after injury, costs of claimants with schedule II opioids averaged [redacted] higher than costs of claimants in the no opioids group. (Volinn, 2009) This large study found that prescription of opioids was common among patients with back pain, and increasing duration of opioid use was strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse); almost 50% of patients receiving long-term opioids had at least one of these diagnoses. Similarly, negative health habits (obesity, smoking) were associated with duration of opioid use. The wisdom of long-acting opioid use for chronic pain remains controversial, recommended as

an option. Tramadol is a centrally acting synthetic opioid analgesic and it provides inferior analgesia compared to a combination of Hydrocodone/ acetaminophen. (Turturro, 1998) As of November 2013, Tramadol has been designated a Schedule IV controlled substance. (DEA, 2013) Tramadol has unreliable analgesic activity and potential side effects such as serotonin syndrome. (Ray, 2013) Tramadol ER is an extended release opioid, but unlike other ER opioids, the FDA labeling limits dosing to a maximum clinical dose of 400 mg/day (equivalent to 80 MED, within the ODG guidelines that dosing not exceed 100 mg MED, see Opioids, dosing). (FDA, 2014) The DEA announced that, effective August 18, 2014, Tramadol and Tramadol ER will be placed into Schedule 4 (low potential for abuse) of the federal Controlled Substances Act. Other ER opioids are Schedule 2 (high potential for abuse).In this case, the patient has been on opiates for at least several months and there is documentation of improved function with ADLs and decreased pain. However, they are not recommended for long term use. A recent approval of a modified amount of medication was noted for weaning purposes. Therefore, based on ODG guidelines and the information in this case, the retro request for Tramadol 150 mg #60 dispensed on 10/28/15 is not medically necessary.