MAXIMUS Federal Services

Case Number:	CM14-0090359		
Date Assigned:	07/23/2014	Date of Injury:	07/14/2006
Decision Date:	11/12/2015	UR Denial Date:	06/12/2014
Priority:	Standard	Application Received:	06/16/2014

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

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 July 14, 2006, incurring low back injuries. He was diagnosed with lumbar degenerative disc disease with disc herniation and lumbar stenosis. On August 14, 2006, a Magnetic Resonance Imaging revealed lumbar disc protrusion with neural foraminal stenosis. He underwent a lumbar laminectomy and fusion. Treatment included pain medications, topical analgesic patches, sleep aides, lumbar epidural steroid injection, H-wave device and activity restrictions and modifications. Currently, the injured worker complained of persistent low back pain radiating into both legs rating his pain with medications 7 out of 10 and without medications 9 out of 10 on a pain scale from 1 to 10. He noted the pain medications, worked well but caused gastrointestinal discomfort. He noted some sleep loss due to the chronic pain. The treatment plan that was requested for authorization included prescriptions for Percocet 10-325 mg, #45 and Ambien CR 12.5 mg, #30. On June 11, 2014, a request for Percocet and Ambien were denied by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Percocet 10/325mg #45: 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): Medications for chronic pain, Opioids, criteria for use, Opioids for chronic pain.

Decision rationale: Based on the 5/5/14 progress report provided by the treating physician, this patient presents with back pain radiating from low back down bilateral legs, and lower backache. The treater has asked for PERCOCET 10/325MG #45 on 5/5/14. The patient's diagnoses per request for authorization dated 5/23/14 are disc disorder lumbar, spinal/lumbar DDD, low back pain, post lumbar laminect syndrome, mood disorder other dis. The patient states that pain level has decreased since last visit, with no changes in location of pain per 3/31/14 report. The patient is s/p caudal epidural steroid injection from February 2014 with benefit at this time, with bilateral lower extremities remaining minimal since the injection per 5/5/14 report. The patient is s/p lumbar MRI from June 2011 that shows a lower L-spine surgery, unspecified. The patient is using Lidoderm patches, Pepcid, Ambien, and Norco as of 3/31/15 report. The patient's work status is permanent and stationary and not currently working as of 5/5/14 report. MTUS, criteria for use of opioids Section, pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, criteria for use of opioids Section, page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS, criteria for use of opioids Section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, medications for chronic pain Section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." MTUS, opioids for chronic pain Section, pages 80 and 81 states that "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." MTUS, opioids for chronic pain Section, page 81: "Nociceptive Pain: Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." The treater does not discuss this request in the reports provided. Review of reports do not show prior use of Percocet. However, the patient has had long term use of opiates, and has been taking Norco since 9/10/12 and in reports dated 6/3/12, 12/16/13, and 3/31/15. The patient is able to go shopping and do house cleaning duties, and can stand for 10 minutes and sit for 15 minutes at a time with the help of Norco per 3/31/15 report. The patient notes 30% reduction in pain with Norco per 3/31/15 report. The patient states he has withdrawal symptoms with Norco, and is less effective than before per 5/5/14 report. All lab work from April 2012 was WNL although a urine drug screen from 1/14/13 was positive for Oxycodone which was not prescribed. This initiating prescription for Percocet would be indicated as the treater has addressed the 4A's and explain why the patient requires a change from Norco to Percocet. However, MTUS pg. 80 states that there is no

evidence that radiculopathy should be treated with opiates, and also states that the efficacy of opiate use for chronic low back pain beyond 16 weeks is unclear and limited. Long-term use of opiates may be indicated for nociceptive pain in certain situations as MTUS pg. 81 states: "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." In this case, the patient does not present with pain that is presumed to be maintained by continual injury resulting in nociceptive pain. Long-term use of opiates is not supported for chronic low back pain. Therefore, the request is not medically necessary.

Ambien CR 12.5mg #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): Zolpidem, 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) Mental Illness and Stress Chapter under Zolpidem (Ambien).

Decision rationale: Based on the 5/5/14 progress report provided by the treating physician, this patient presents with back pain radiating from low back down bilateral legs, and lower backache. The treater has asked for AMBIEN CR 12.5MG #30 on 5/5/14. The patient's diagnoses per request for authorization dated 5/23/14 are disc disorder lumbar, spinal/lumbar DDD, low back pain, post lumbar laminect syndrome, mood disorder other dis. The patient states that pain level has decreased since last visit, with no changes in location of pain per 3/31/14 report. The patient is s/p caudal epidural steroid injection from February 2014 with benefit at this time, with bilateral lower extremities remaining minimal since the injection per 5/5/14 report. The patient is s/p lumbar MRI from June 2011 that shows a lower L-spine surgery, unspecified. The patient is using Lidoderm patches, Pepcid, Ambien, and Norco as of 3/31/15 report. The patient's sleep is poor but "sleep is improved on most nights with use of Ambien" per 2/17/15 report. The patient's work status is permanent and stationary and not currently working as of 5/5/14 report. ODG-TWC, Mental Illness and Stress Chapter under Zolpidem (Ambien) states: "Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment for zolpidem (brand names Ambien, Edluar, Intermezzo, Zolpimist). See also the Pain Chapter. Zolpidem is approved for the short-term (usually two to six weeks) treatment of insomnia. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. Ambien CR offers no significant clinical advantage over regular release zolpidem, and Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. Due to adverse effects, FDA now requires lower doses for zolpidem. The ER product is still more risky than IR. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (Pain Chapter) Emergency department (ED) visits for adverse reactions related to zolpidem increased

by almost 220% in a recent 5-year period, according to the Substance Abuse and Mental Health Services Administration (SAMHSA). Women and the elderly appear to be most prone to adverse reactions linked to zolpidem. Doctors should look at alternative strategies for treating insomnia such as sleep hygiene. By 2010 there were 64,175 ED visits involving zolpidem. The report stresses that zolpidem should be used safely for only a short period of time." Ambien CR has been included in patient's medications as early as 12/16/13 report, and in subsequent reports dated 3/31/15 and 5/5/14. The requesting 5/5/14 report states "increase [Ambien] from 6.25 to 12.5mg to address patient waking up frequently throughout the night." ODG does not recommend long-term use of Ambien CR. ODG states Ambien CR does not have due any clinical advantage over regular release Zolpidem and it is not recommended for long term use due to negative side effect profile. In this case, the patient has been prescribed Ambien CR for more than 5 months from UR date of 6/12/14. The current request for continued use of Ambien CR at an increased dose is not in accordance with ODG indications. Therefore, the request IS NOT medically necessary.