

Case Number:	CM15-0210166		
Date Assigned:	10/29/2015	Date of Injury:	08/11/2004
Decision Date:	12/14/2015	UR Denial Date:	09/17/2015
Priority:	Standard	Application Received:	10/26/2015

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

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 68 year old female, who sustained an industrial injury on August 11, 2004. She reported a cumulative work injury. The injured worker was currently diagnosed as having lumbosacral sprain with degenerative joint disease with spondylolisthesis defect at L4-L5 with radicular symptoms in the left leg with disc herniation and insomnia due to pain. Treatment to date has included diagnostics studies and medications. Zanaflex was included in the treatment plan on July 2, 2007 and Ambien was included in the treatment plan on September 27, 2007. Flector patches were prescribed on March 13, 2012. On October 8, 2015, the injured worker complained of back pain that was reported to be getting worse along with shooting pain in her left hip down her leg. She also reported burning pain that radiates in the right leg. She stated that she cannot function without pain medication and reported 50% reduction in pain and functional improvement with activities of daily living with the medications versus not taking them at all. She rated her pain as a on a 1-10 pain scale with medications and a 10 on the pain scale without them. On the day of exam, her medication regimen included Ultram, Zanaflex, Flector anti-inflammatory patch and Ambien. The treatment plan included continuation of medications, urine drug screen and a re-evaluation. On September 17, 2015, utilization review denied a request for Zanaflex 4mg #45, Flector patches 1.3% #60 and Ambien CR 6.25 #30. A request for Ultram ER 200mg #30 was authorized.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tizanidine (Tizanidine Hydrochloride Tablet) - 4mg #45 (Zanaflex 4mg #45): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Based on the 9/8/15 progress report provided by the treating physician, this patient presents with worsening back pain shooting into the left hip more than right, with burning sensation in the right leg, rated 8/10 currently, 4/10 with medications, and 10/10 without medications. The treater has asked for Tizanidine (Tizanidine Hydrochloride Tablet) - 4mg #45 (Zanaflex 4mg #45) on 9/8/15. The patient's diagnosis per request for authorization dated 9/11/15 is lumbar DJD. The patient reports a 50% reduction in pain and functional improvement with activities of daily living when using medications versus not taking them at all per 5/15/15 report. The patient does not have a history of surgeries per review of reports. The patient also reports having insomnia due to back pain, but is stable with Ambien per 7/9/15 report. The patient is currently not working, and is on Social Security Disability per 7/9/15 report. MTUS Guidelines, Muscle Relaxants for pain section, pg 66 states the following: Tizanidine is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. One study -conducted only in females demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. MTUS Guidelines, Medications for Chronic Pain section, pg. 60, 61 states: "Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference...Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded (Mens, 2005)." The treater does not discuss this request in the reports provided. The patient has been taking Zanaflex as early as a 7/2/07, and has been taking it continuously for over 8 years. The patient is currently taking Zanaflex "for muscle relaxation" per 9/8/15 report. She occasionally takes Zanaflex for severe muscle spasms and "finds these helpful" per 5/21/13 report. But in the past 2 years of use, there has not been any recent documentation of a reduction in pain or improvement in function as required by MTUS pg. 60. In addition, the patient does not have a diagnosis of myofascial pain as per MTUS guidelines. Given the lack of documentation of efficacy, the continued use of Zanaflex is not supported. This request is not medically necessary.

Diclofenac Epolamine (Flector Patch) #60 (Flector patches 1.3% #60): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain - Flector Patches.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Based on the 9/8/15 progress report provided by the treating physician, this patient presents with worsening back pain shooting into the left hip more than right, with burning sensation in the right leg, rated 8/10 currently, 4/10 with medications, and 10/10 without medications. The treater has asked for Diclofenac Epolamine (flector patch) #60 (flector patches 1.3% #60) on 9/8/15. The patient's diagnosis per request for authorization dated 9/11/15 is lumbar DJD. The patient reports a 50% reduction in pain and functional improvement with activities of daily living when using medications versus not taking them at all per 5/15/15 report. The patient does not have a history of surgeries per review of reports. The patient also reports having insomnia due to back pain, but is stable with Ambien per 7/9/15 report. The patient is currently not working, and is on Social Security Disability per 7/9/15 report. MTUS, Topical Analgesics Section, pg 111-113 states, "Indications: Osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." Per progress report dated 9/22/15, the treater states that the patient is currently using Flector patches. The patient has been prescribed Flector Patches since 6/4/12 report and has been using them continuously for over 3 years. In this case, the patient has a diagnosis of lumbar degenerative joint disease and spondylolisthesis defect at L4-5, but does not present with peripheral joint arthritis/tendinitis, for which a topical NSAID would be indicated. This patient presents with back pain, for which topical NSAIDs are not supported. Therefore, the request is not medically necessary.

Zolpidem (Ambien CR Tablet, Coated) - 6.25mg #30 (Ambien CR 6.25mg #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 - Ambien (Zolpidem) <http://www.drugs.com/pro/ambien.html>.

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.

Decision rationale: Based on the 9/8/15 progress report provided by the treating physician, this patient presents with worsening back pain shooting into the left hip more than right, with burning sensation in the right leg, rated 8/10 currently, 4/10 with medications, and 10/10 without medications. The treater has asked for Zolpidem (Ambien CR tablet, coated) 6.25mg #30 (Ambien CR 6.25mg #30 on 9/8/15. The patient's diagnosis per request for authorization dated 9/11/15 is lumbar DJD. The patient reports a 50% reduction in pain and functional improvement with activities of daily living when using medications versus not taking them at all per 5/15/15 report. The patient does not have a history of surgeries per review of reports. The patient also reports having insomnia due to back pain, but is stable with Ambien per 7/9/15 report. The patient is currently not working, and is on Social Security Disability per 7/9/15 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 6.25mg was initiated on 9/27/07 report, and it has been in use continuously for over 8 years. The patient was first given Ambien CR 12.5mg on 10/22/07 but found it was sedating, and so the treater reduced dosage to Ambien CR 6.25mg. Review of reports does not show any documentation of benefit from this medication. 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 8 years. The current request for continued use of Ambien CR is not in accordance with ODG indications. Therefore, the request is not medically necessary.