

<b>Case Number:</b>	CM15-0195394		
<b>Date Assigned:</b>	10/09/2015	<b>Date of Injury:</b>	11/09/1995
<b>Decision Date:</b>	12/11/2015	<b>UR Denial Date:</b>	09/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/05/2015

### 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: Emergency 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 55-year-old male, with a reported date of injury of 11-09-1995. The diagnoses include lumbar postlaminectomy syndrome, single episode unspecified major depression, lumbar disc displacement without myelopathy, and recurrent episode unspecified major depression. Treatments and evaluation to date have included bilateral transforaminal lumbar epidural steroid injection at L3-4 and L4-5, Viagra (since at least 04-2015), Cymbalta, Fioricet-Butalbital-Acetaminophen-Caffeine (since at least 04-2015), Ambien (since at least 04-2015), Baclofen (since at least 04-2015), Ketamine cream (since at least 04-2015), Morphine sulfate, lumbar laminectomy and fusion in 2002. The diagnostic studies to date have included a CT scan of the lumbar spine on 07-23-2015 which showed disc degeneration at L5-1 with osteophyte and moderate bilateral facet arthropathy that caused marked bilateral lateral recess stenosis and moderately severe bilateral foraminal stenosis, L4-5 posterior fusion with bilateral pedicle screw and rod fixation in normal alignment, and L3-4 mild bilateral facet arthropathy with thickened ligament flava and retrolisthesis; an MRI of the lumbar spine on 06-15-2015 which showed trace degenerative retrolisthesis at L3-4 with annular bulge and facet degenerative change, bilateral foraminal narrowing, and annular bulge and endplate ridging at L5-S1 with bilateral foraminal narrowing; and a urine drug screen on 07-23-2015 which was positive for Barbiturates and opiates. The visit note dated 08-28-2015 indicates that the injured worker underwent a bilateral transforaminal lumbar epidural steroid injection at L3-4 and L4-5. He stated that he had a reduction in pain from a rating of 9 out of 10 down to 4 out of 10. He also stated that he had the most pain relief in the low back. The injured worker also had a

decrease in the numbness into the lower extremity in the back of the thigh. He reported sleeping better at night and had less pain with walking. The objective findings include an antalgic gait; normal muscle tone without atrophy in the bilateral upper and lower extremities; and normal bilateral lower extremity flexion and extension. It was noted that there was no aberrant behavior regarding the injured worker's opioid medication. The treatment plan included the refilling of the medications. The treating physician stated that the Ambien helped the injured worker to sleep; and the Fioricet helped to minimize the intensity of the headaches. The injured worker was permanent and stationary. The request for authorization was dated 09-02-2015. The treating physician requested Ketamine 5% cream 60 grams #2; Baclofen 10mg #90; Fioricet- Butalbital-Acetaminophen-Caffeine #60; Ambien CR 12.5mg #30; and Viagra 100mg #30. On 09-11-2015, Utilization Review (UR) non-certified the request for Ketamine 5% cream 60 grams #2; Baclofen 10mg #90; Fioricet-Butalbital-Acetaminophen-Caffeine #60; Ambien CR 12.5mg #30; and Viagra 100mg #30.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Ketamine 5% cream 60 grams #2:** Upheld

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

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

**Decision rationale:** The request is for the use of Ketamine for topical use to aid in pain relief. The MTUS guidelines state the following regarding its use: "Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also Glucosamine (and Chondroitin Sulfate)." In this case, the use of this product is not indicated for the indication listed. This is secondary to poor scientific evidence of efficacy for the patient's condition when applied topically. As such, the request is not medically necessary.

**Baclofen 10 mg #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line

option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

**Fioricet-Butalbital/APAP/Caffeine #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Barbiturate-containing analgesic agents.

**Decision rationale:** The request is for the use of a barbiturate containing analgesic medication. The MTUS states the following regarding this topic: Not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) There is a risk of medication overuse as well as rebound headache (Friedman, 1987). In this case, as indicated above, the use of this medication is not recommended. Any barbiturate medication is not advised for chronic pain and has a high abuse potential. As such, the request is not medically necessary.

**Ambien CR 12.5 mg #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 (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental (stress)/ Zolpidem (Ambien).

**Decision rationale:** The request is for the use of zolpidem. The official disability guidelines state the following regarding the use of this medication: 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. (SAMHSA, 2013) Zolpidem (Ambien) increases the ability to remember images, but only those that have negative or highly arousing content. The findings have potential ramifications for patients prescribed zolpidem for relief of insomnia due to anxiety disorders, including posttraumatic stress disorder (PTSD). Physicians should watch out for this counter therapeutic effect in patients with anxiety disorders and PTSD, because these are people who already have heightened memory for negative and high-arousal memories. The study also identified sleep spindles as the mechanism that enables the brain to consolidate emotional memory. Sleep spindles are brief bursts of brain activity that occur primarily during non-rapid eye movement (REM) sleep. (Kaestner, 2013) New analysis from SAMHSA shows that overmedicating with zolpidem led to a near doubling of emergency department (ED) visits during the periods 2005-2006 and 2009-2010. (SAMHSA, 2014) In this case, zolpidem is not indicated. This is secondary to the prolonged duration of use. As such, the request is not medically necessary.

**Viagra 100 mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [http://www.medscape.com/viewarticle/542736\\_4](http://www.medscape.com/viewarticle/542736_4).

**Decision rationale:** The request is for a medication used for erectile dysfunction. The MTUS and ODG are silent regarding this issue. The alternate source states that medications classified as PDE5 inhibitors are the recommended first-line treatment for erectile dysfunction. Prior to use, a urologic exam is indicated along with a review of the patient's medications to categorize the type of sexual dysfunction and make sure that it can be used safely. In this case, there is no documentation of a urologic examination and discussion of the etiology including differential diagnosis such as opiate induced testosterone deficiency or vascular insufficiency. Pending receipt of this information, the request is not medically necessary