

<b>Case Number:</b>	CM15-0203579		
<b>Date Assigned:</b>	10/20/2015	<b>Date of Injury:</b>	11/27/1996
<b>Decision Date:</b>	12/29/2015	<b>UR Denial Date:</b>	10/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/16/2015

### 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: Florida, New York, Pennsylvania  
 Certification(s)/Specialty: Family Practice

### 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 63 year old male, who sustained an industrial injury on 11-27-1996. The medical records indicate that the injured worker is undergoing treatment for chronic low back pain, failed lumbar back surgery, lumbar radiculopathy, myalgia, xerostomia, and bilateral shoulder impingement syndrome, erectile dysfunction secondary to medication, testicular hypo-function, chronic anxiety, chronic depression, and chronic insomnia. According to the progress report dated 9-28-2015, the injured worker presented for medication management. He reports that he is not taking his medications as prescribed due to non-certification. The treating physician states, "his sleep and mood have been adversely affected as a result of untreated chronic pain". The pain is located in the bilateral legs, shoulders, buttocks, knees, and low back. The pain is described as constant, sharp, shooting, burning, stabbing, and electrical. On a subjective pain scale, he rates his pain 8 out of 10. The sleep assessment reveals that he falls asleep in 2-3 hours, wakes up 2-3 times. He denies daytime naps and watching TV prior to bedtime. Assessment of his mood is documented as crying, depressed, angry, anxious, and frustrated. The current medications are Chlordiazepoxide, Butrans patch, Fentanyl, Norco, Venlafaxine (since at least 5-26-2015), Ambien (since at least 5-26-2015), Cymbalta, Capsaicin patch, and Terazosin (since at least 5-26-2015). Treatments to date include medication management and surgical intervention. Work status is not indicated. The original utilization review (10-6-2015) partially approved a request for Ambien CR 12.5 mg #10 (original request was for #15) and Ambien 10mg #10 (original request was for #15). The request for Terazosin HCL 5mg #60 and Venflaxaine HCL 75mg #45 was non-certified.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Terazosin HCL 5mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/019057s0221bL.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019057s0221bL.pdf).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Epocrates.com accessed online 23 Dec 15, Annals of Clinical Psychiatry, 25, 2, May 2013, E1-E7, Mago R.

**Decision rationale:** The members DOI is listed as 27 Nov 96 with ongoing treatment for chronic low back pain, failed lumbar spine surgery with radiculopathy, shoulder impingement, myalgia, chronic anxiety, chronic depression and chronic insomnia. The patient's medications had apparently not been certified and he had remained without medications for some time going through withdrawal and with an overall deterioration in function. The pain is rated as 8/10 at baseline rising to 10/10. The member experiences bilateral leg, shoulder, buttock, knee and low back pain. He does not exhibit any urinary symptoms or suggestion of symptoms compatible with BPH. The member was reported to be on Cymbalta 60mg two a day for peripheral LE neuropathic pain and based on a telephone conference with the treating provider attempting to use Terazosin for antidepressant-induced excessive sweating (ADIES) with night sweats (although there was nothing in the supporting documents alluding to this). The MTUS does not cover this scenario. Of note there is no indication in the supporting documentation with reference for the use of this medication for this patient for antidepressant induced excessive sweating. Terazosin has been a longstanding antihypertensive that was found to be effective for symptoms of BPH. Recently an article published on the topic of antidepressant induced excessive sweating in an open-label titration trial found Terazosin to be very and reasonably tolerated. Unfortunately the study has not been replicated in a double blind cross-over study to meet criteria for efficacy. It is not FDA approved for this indication and until further reliable studies become available supporting this as a useful and safe off label use of the medication its use cannot be supported. The request is not medically necessary.

### **Ambien CR 12.5mg #15:** 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, Insomnia treatment.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines. Decision based on Non-MTUS Citation Epocrates.com accessed online 23 Dec 15.

**Decision rationale:** The members DOI is listed as 27 Nov 96 with ongoing treatment for chronic low back pain, failed lumbar spine surgery with radiculopathy, shoulder impingement, myalgia, chronic anxiety, chronic depression and chronic insomnia. The patient's medications had apparently not been certified and he had remained without medications for some time going through withdrawal and with an overall deterioration in function. The pain is rated as 8/10 at baseline rising to 10/10. The member experiences bilateral leg, shoulder, buttock, knee and low back pain. He does not exhibit any urinary symptoms or suggestion of symptoms compatible with BPH. The member was reported to be on Cymbalta 60mg two a day for peripheral LE neuropathic pain and based on a telephone conference with the treating provider attempting to use Terazosin for antidepressant-induced excessive sweating (ADIES) with night sweats (although there was nothing in the supporting documents alluding to this). Benzodiazepine related sedative/hypnotics are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. Both the CR and rapid formulation of Ambien are recommended to have a minimum 7-hour window for use. This suggests use Ambien on top of CR would likely lead to daytime side effects. In addition, the total dose in combination would exceed the manufacturers recommended maximum dosing. A more appropriate treatment for anxiety disorder is an antidepressant in this patient with chronic anxiety and chronic depression. In addition, with chronic insomnia an appropriate anti-depressant would be preferred. Abrupt withdrawal is to be avoided per the manufacturer's recommendations to prevent a withdrawal syndrome. Therefore, this request is not medically necessary.

**Venflaxaine HCL 75mg #45:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain, SNRIs (serotonin noradrenaline reuptake inhibitors).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Venlafaxine (Effexor). Decision based on Non-MTUS Citation Epocrates.com assessed online 23 Dec 15.

**Decision rationale:** The members DOI is listed as 27 Nov 96 with ongoing treatment for chronic low back pain, failed lumbar spine surgery with radiculopathy, shoulder impingement, myalgia, chronic anxiety, chronic depression and chronic insomnia. The patient's medications had apparently not been certified and he had remained without medications for some time going through withdrawal and with an overall deterioration in function. The pain is rated as 8/10 at baseline rising to 10/10. The member experiences bilateral leg, shoulder, buttock, knee and low back pain. He does not exhibit any urinary symptoms or suggestion of symptoms compatible with BPH. The member was reported to be on Cymbalta 60mg two a day for peripheral LE neuropathic pain and based on a telephone conference with the treating provider attempting to use Terazosin for antidepressant-induced excessive sweating (ADIES) with night sweats (although there was nothing in the supporting documents alluding to this). Venlafaxine is recommended as an option in first-line treatment of neuropathic pain. Venlafaxine is a member

of the selective-serotonin and norepinephrine reuptake inhibitor (SNRIs) class of antidepressants. It has FDA approval for treatment of depression and anxiety disorders, diabetic neuropathy and fibromyalgia. It is off-label recommended for treatment of neuropathic pain and headaches. While the Cymbalta is being used, according to the PCM, specifically for the LE neuropathic pain per the notes the member is not under control from his anxiety, depression and insomnia. All these symptoms play a part in impairing his ability to deal with and better manage his ongoing neuropathic pain. There is no contra-indication to the use of Venlafaxine and Cymbalta. It may in fact augment the management of neuropathic pain as well. Therefore, this request is medically necessary.

**Ambien 10mg #15: 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, Insomnia treatment.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines. Decision based on Non-MTUS Citation Epocrates.com accessed online 23 Dec 15.

**Decision rationale:** The members DOI is listed as 27 Nov 96 with ongoing treatment for chronic low back pain, failed lumbar spine surgery with radiculopathy, shoulder impingement, myalgia, chronic anxiety, chronic depression and chronic insomnia. The patient's medications had apparently not been certified and he had remained without medications for some time going through withdrawal and with an overall deterioration in function. The pain is rated as 8/10 at baseline rising to 10/10. The member experiences bilateral leg, shoulder, buttock, knee and low back pain. He does not exhibit any urinary symptoms or suggestion of symptoms compatible with BPH. The member was reported to be on Cymbalta 60mg two a day for peripheral LE neuropathic pain and based on a telephone conference with the treating provider attempting to use Terazosin for antidepressant-induced excessive sweating (ADIES) with night sweats (although there was nothing in the supporting documents alluding to this). Benzodiazepine related sedative/hypnotics are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. Both the CR and rapid formulation of Ambien are recommended to have a minimum 7-hour window for use. This suggests use Ambien on top of CR would likely lead to daytime side effects. In addition, the total dose in combination would exceed the manufacturers recommended maximum dosing. A more appropriate treatment for anxiety disorder is an antidepressant. In this patient with chronic anxiety and chronic depression. In addition, with chronic insomnia an appropriate anti-depressant would be preferred. Abrupt withdrawal is to be avoided per the manufacturer's recommendations to prevent a withdrawal syndrome. Therefore, this request is not medically necessary.