

<b>Case Number:</b>	CM15-0075067		
<b>Date Assigned:</b>	04/24/2015	<b>Date of Injury:</b>	08/29/2005
<b>Decision Date:</b>	06/10/2015	<b>UR Denial Date:</b>	04/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/20/2015

### 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: New York  
 Certification(s)/Specialty: Anesthesiology

### 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 56 year old male, who sustained an industrial injury on 8/29/2005. Diagnoses have included compound fracture of the right distal tibia and fibular status post open reduction and external fixation, chronic pain syndrome, suspected complex regional pain syndrome (CRPS) type II, chronic low back pain and narcotic-related sedation. Treatment to date has included transcutaneous electrical nerve stimulation (TENS) and medication. According to the progress report dated 2/23/2015, the injured worker had recently attempted to taper himself off of Lyrica and noted increased neuropathic pain in the right lower extremity. The injured worker's tolerance for weight bearing activities was approximately five minutes with the use of medications and approximately two minutes without medications. The injured worker complained of chronic right lower extremity pain. Exam of the lumbar spine revealed tenderness to palpation in the right lumbar paraspinal region and the lower lumbar spine. Authorization was requested for Opana, Dilaudid, Provigil and Ambien CR.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Opana ER 40mg #180: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines On-going management, When to discontinue/Continue Opioids, Opioids, dosing, Weaning of medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for the treatment of chronic pain Page(s): 91-97.

**Decision rationale:** Opana ER (Hydromorphone/Dilaudid) is a semi-synthetic opioid analgesic which affects the central nervous system and is indicated for the treatment of moderate to severe pain. According to California MTUS Guidelines, certain criteria need to be followed, including an ongoing review and documentation of pain relief and functional status, appropriate medication use and side effects. Pain assessment should include current pain: last reported pain over the period since last assessment; average pain; intensity of pain after taking the opiate, and the duration of pain relief. In this case, the claimant stated that there was functional improvement with this medication. However, there was no evidence of objective functional improvement supporting the subjective findings stated. There has been no documentation of this medication's analgesic effectiveness and no clear documentation that the patient has responded to ongoing opioid therapy. Without this documentation, medical necessity has not been established. The requested treatment with Opana ER is not medically necessary.

**Dilaudid 4mg #180:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Dilaudid.

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

**Decision rationale:** According to the ODG, chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. When these drugs do not satisfactorily reduce pain, opioid analgesics for moderate to severe pain, such as Dilaudid, may be added. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's pain relief effectiveness, functional status, or response to ongoing opioid analgesic therapy. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Provigil 100mg #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), Pain (Chronic).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine 2014: Provigil.

**Decision rationale:** Provigil (Modanafil) is a wakefulness-promoting agent that is FDA approved for the treatment of wakefulness disorders such as narcolepsy, shift work disorder, and excessive daytime sleepiness associated with obstructive sleep apnea. In this case, the medication is being prescribed to counteract the effects of narcotics. The medication is not approved for this use. There is no documentation indicating the patient has any condition requiring the use of Provigil. Medical necessity for the requested medication has not been established. The requested medication 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 (ODG), Pain (Chronic).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Insomnia treatment.

**Decision rationale:** Ambien (Zolpidem) is a prescription short-acting non-benzodiazepine hypnotic, which is recommended for short-term treatment of insomnia (two to six weeks). Ambien is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. Longer-term studies have found Ambien to be effective for up to 24 weeks in adults. It can be habit-forming, and may impair function and memory more than opioid analgesics. There is also concern that Ambien may increase pain and depression over the long-term. The treatment of insomnia should be based on the etiology, and pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. In this case, Ambien CR has been used since at least 2013 and the guidelines do not support long-term use of this medication. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.