MAXIMUS Federal Services

| Case Number: | CM14-0137938 | | |
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| Date Assigned: | 09/05/2014 | Date of Injury: | 10/19/2009 |
| Decision Date: | 10/29/2014 | UR Denial Date: | 08/18/2014 |
| Priority: | Standard | Application Received: | 08/26/2014 |

## 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. The expert reviewer is Board Certified in Neurology and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

## 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 (IW) is a 39 year-old female with a reported date of injury as 10/19/2009. The mechanism of injury is reported to be trauma to the neck and left arm and left shoulder when the IW was assaulted during a robbery in the jewelry store where she worked. The clinical reports provided for this review indicate that the IW is status post two-level cervical fusion (C5-C7) performed in 2010 but has continuing pain complaints in her left neck and left shoulder with left lower extremity weakness, numbness, and tingling. Current diagnoses are degeneration of cervical vertebral discs and cervical post-laminectomy syndrome. A cervical spine MRI dated 4/9/2014 indicates a previous C5-7 fusion and a posterior osteophyte from the C5 mid-vertebral body possibly extending into the central canal and possibly contacting the descending left C6 nerve root. An EMG study on 4/15/2014 indicated a left C5/6 radiculopathy without entrapment neuropathy, peripheral neuropathy, nor brachial plexopathy. Medical encounter reports dating back to 2/25/2014 indicate that the IW's pain complaints are being treated with opioid therapy (Opana 10 mg every six hours, four times daily; Opana ER 40 mg every 8 hours, three times daily) and sleep disturbances due to pain are being addressed Ambien CR (12.5 mg) each night. Clinical Encounter Summaries on 6/12/2014 and 8/8/2014 indicate that the IW desires to decrease dependency on opiates and that a detoxification program will be required. The Clinical Encounter Summaries submitted are absent of the following documentation: Urine toxicology screens, indications of pain status pursuant to opiate doses, an opioid treatment contract, or assessments of functional improvement. Recurrent Requests For Authorization for Ambien 12.5 mg, Opana 10 mg (4x/day) and Opana ER 40 mg (3x/day) dating back to 2/25/2014 have been approved only on a modified basis each time for the purpose of weaning, since 3/12/2014 -- per Utilization Reviews (URs) dated 3/12/2014, 4/2/2014, 5/9/2014, 6/17/2014, and 8/18/2014. The

UR dated 4/2/2014 provided detail specific for a dosing program appropriate for reducing opioid use and eventual weaning.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Ambien CR 12.5mg #30:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Insomnia Treatment Other Medical Treatment Guideline or Medical Evidence: Up-to-Date, Zolpidem, 10/24/2014

**Decision rationale:** Per the ODG Pain Chapter, Insomnia Treatment: Zolpidem is a benzodiazepine-receptor agonist with sedative and hypnotic properties used for the short-term treatment (7 -10 days) insomnia. Ambien CR is a proprietary controlled-release formulary of Zolpidem which is indicated specifically for the treatment of delayed sleep-onset and for the maintenance of sleep once achieved. While trials have indicated that Ambien CR may be effective for up to 24 weeks of treatment, the only FDA-approved benzodiazepine-receptor agonists for use greater than 35 days is Eszopicolone (Lunesta). All benzodiazepine-receptor agonists are schedule IV controlled substance and carry the potential for abuse and dependency. Furthermore, pharmacokinetic studies involving zolpidem showed a significant increase in maximum concentration and exposure in females compared to males at the same dose; the recommended dose for females taking the controlled-release formulary is 6.25 mg, whereas the higher 12.5 mg dose is indicated as a maximum dose for some male patients (Up-To-Date, Zolpidem: Dosing, Precautions/Warnings, 10/24/2014). As this IW has been using Ambien CR 12.5 mg continuously for a duration which exceeds the limit indicated by the ODG (i.e., Lunesta is the only FDA-approved agent in this class for use > 35 days), and since the dosing is greater than that recommended for female patients, the request for Ambien 12.5 mg #30 is not medically necessary.

**Opana 10mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-97.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Dosing Page(s): 74 - 96, 86-87.

**Decision rationale:** With regard to use of opioids for the treatment of chronic pain, the MTUS is specific to note that it is not recommended that dosing exceed 120 mg oral morphine equivalents per day (Opioids, dosing, p.86-87). When taking more than one opioid, such as a short-acting opioid (like Opana) and an extended-release opioid (such as Opana ER), the equivalent doses

should be summed to calculate the cumulative dose, or the Morphine Equivalent Dose (MED) per day. The requested dosing for Opana is 10 mg four times daily, or 120 MEDs. The requested dosing for Opana ER is 40 mg three times daily, or 360 MEDs. Combined, the MEDs prescribed for this patient sums to 480, and exceeds the limit recommended by the MTUS. In such exceptional and rare cases where opioid therapy is required beyond this recommended limit, it is expected that a pain management consultation has been rendered, but there is no evidence that such has been obtained. The documentation submitted for this review does not include any substantiation whether by detailing the functional improvements or pain modification via a validated assessment measures which could justify this dosing. There is no mention of opioid treatment management measures such as periodic urine drug screens nor a pain treatment contract. Previous Utilization Reviews have serially modified these requests for this opioid treatment to allow for weaning. Since adequate medication has been provided for this purpose in several prior Utilization Reviews, it is not medically necessary to certify the Opana 10 mg and Opana ER 40 mg as requested.

**Opana ER 40mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-97.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Dosing Page(s): 74-96 86-87.

**Decision rationale:** With regard to use of opioids for the treatment of chronic pain, the MTUS is specific to note that it is not recommended that dosing exceed 120 mg oral morphine equivalents per day (Opioids, dosing, p.86-87). When taking more than one opioid, such as a short-acting opioid (like Opana) and an extended-release opioid (such as Opana ER), the equivalent doses should be summed to calculate the cumulative dose, or the Morphine Equivalent Dose (MED) per day. The requested dosing for Opana is 10 mg four times daily, or 120 MEDs. The requested Opana ER 40 mg three times daily, or 360 MEDs. Combined, the MEDs prescribed for this patient sums to 480, and exceeds the limit recommended by the MTUS. In such exceptional and rare cases where opioid therapy is required beyond this recommended limit, it is expected that a pain management consultation has been tendered, but there is no evidence that such has been contracted. The documentation submitted for this review does not include any substantiation whether by detailing the functional improvements or pain modification via a validated assessment measures which could justify this dosing. There is no mention of opioid treatment management measures such as periodic urine drug screens nor a pain treatment contract. Previous Utilization Reviews have serially modified these requests for this opioid treatment to allow for weaning. Since adequate medication has been provided for this purpose in several prior Utilization Reviews, it can be assumed that it is not medically necessary to certify the Opana 10 mg and Opana ER 40 mg as requested.