

<b>Case Number:</b>	CM13-0063863		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	11/03/2006
<b>Decision Date:</b>	07/30/2014	<b>UR Denial Date:</b>	12/04/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/10/2013

### 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 Anesthesiology and Pain Medicine and is licensed to practice in Florida. 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 is a 30-year-old male who reported an injury on 11/03/2006, with the mechanism of injury not cited within the documentation provided. In the clinical notes dated 11/26/2013, the injured worker complained of low back pain that radiated to the bilateral lower extremities. He also complained of neck pain that radiated to the bilateral upper extremities. The injured worker rated his pain level status at a 7/10, with medications and a 10/10 without medications. It was noted that the injured worker reported limited activities of daily living, to include ambulation, hand function, sleep and sex. It was also noted that the injured worker complained of gastrointestinal (GI) upset and that his primary treating physician had requested inpatient detox for the injured worker. Prior treatments included prescribed medications and physical therapy. The physical examination of the lumbar spine revealed moderate reduction in range of motion, secondary to pain. It was also noted that there was tenderness to the spinal vertebrae at the L4-S1 level. There was also lumbar myofascial tenderness and paraspinous muscle spasm upon palpation. The physical examination of the cervical spine revealed a moderate reduction of range of motion secondary to pain. It was noted that there was tenderness to the spinal vertebrae at the C4-7 level. It was also noted that there was cervical myofascial tenderness upon palpation. The diagnoses included lumbar radiculopathy; cervical radiculopathy; myalgia/myositis; iatrogenic opioid dependency; chronic pain, other; medication-related dyspepsia; and bilateral shoulder pain. The treatment plan included a follow-up in the clinic in one (1) month for a re-evaluation; prescribed medications of clonidine HCl, Protonix DR 20 mg, loratadine 10 mg one (1) tablet one (1) time daily for 30 days #30, Opana ER 40 mg one (1) tab by mouth every eight (8) hours for 30 days #90, oxycodone HCl 30 mg tablet one (1) tablet every eight (8) hours for pain for 30 days #90 and Neurontin 300 mg capsule one (1) by

mouth daily for 30 days #30. The Request for Authorization for loratadine 10 mg #30, lidocaine HCl 2% gel and Opana extended-release (ER) 40 mg #90 was not submitted.

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

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

#### **Loratadine 10mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.rxlist.com/claritin-drug.htm](http://www.rxlist.com/claritin-drug.htm).

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

**Decision rationale:** The Official Disability Guidelines (ODG) state that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next day sedation has been noted, as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision or orthostatic hypertension, dizziness, palpitations, an increase in liver enzymes, drowsiness, dizziness, grogginess and tiredness. In the clinical notes provided for review, there is a lack of documentation of the rationale for the use of loratadine tablets. It is documented that the injured worker has limitations of sleep; however, the use of sleep aids is not addressed within the clinical notes. Therefore, the request for loratadine 10 mg #30 is not medically necessary.

#### **Lidocaine HCL 2% gel: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112.

**Decision rationale:** The Chronic Pain Guidelines state that topical analgesics are largely experimental in use, with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Lidocaine is indicated for neuropathic pain and recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Topical lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially-approved topical formulations of lidocaine (rather creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and antipruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. In the clinical notes provided for review, there is a lack of documentation of the injured worker stating the efficacy of prior topical pain

analgesics. There is also a lack of documentation of the request for lidocaine HCl 2% being made within this clinical note. Furthermore, the frequency is not specified. Therefore, the request for lidocaine HCl 2% gel is not medically necessary.

**Opana Extended-Release (ER) 40mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain; Opioids, specific drug list Page(s): 80, 93.

**Decision rationale:** The Chronic Pain Guidelines state that opioids for chronic pain are suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for the treatment of chronic lumbar pain with resultant neuropathy. Opana extended-release (ER) is not intended for as needed use. Injured workers are to avoid alcohol while on Opana ER, due to increased (possibly fatal) plasma levels. In the clinical notes provided for review, it is indicated that the injured worker's primary care physician had requested for inpatient detox. As such, there is a lack of documentation of the weaning schedule for the injured worker. Furthermore, there is a lack of documentation of the injured worker having tried first-line recommendations, such as antidepressants or anticonvulsants with or without efficacy. Therefore, the request for Opana ER 40 mg #90 is not medically necessary.

**Oxycodone 30mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain; Opioids, specific drug list Page(s): 80, 92.

**Decision rationale:** The Chronic Pain Guidelines indicate that opioids for chronic pain have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for the treatment of chronic lumbar pain with resultant neuropathy. Oxycodone is indicated for moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. In the clinical notes provided for review, it is annotated that the injured worker is also on Opana extended-release (ER) 40mg every eight (8) hours. In conjunction with the use of oxycodone 30 mg one (1) tab every eight (8) hours, this greatly exceeds the recommended morphine equivalent dosage of 120 mg. Therefore, the request for oxycodone 30 mg #90 is not medically necessary.