

<b>Case Number:</b>	CM15-0167553		
<b>Date Assigned:</b>	09/08/2015	<b>Date of Injury:</b>	09/11/2012
<b>Decision Date:</b>	10/23/2015	<b>UR Denial Date:</b>	08/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/25/2015

### 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: Physical Medicine & Rehabilitation

### 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 32 year old male, who sustained an industrial injury on September 11, 2012. He reported low back pain. The injured worker was diagnosed as having sprain of the lumbar region, degeneration of the lumbar or lumbosacral intervertebral disc, sciatica, lumbar radicular pain, lumbar spinal stenosis, lumbar disc herniation, low back pain and chronic pain syndrome. Treatment to date has included diagnostic studies, home exercises, epidural steroid injections (ESI), conservative care and activity restrictions. Currently, the injured worker continues to report right sided low back pain. The injured worker reported an industrial injury in 2012, resulting in the above noted pain. He was treated conservatively without complete resolution of the pain. Evaluation on February 24, 2015, revealed continued pain as noted. He rated his pain at 6 without medications and 1 with medications on a scale of 1-10 with 10 being the worst. Medications including Norco and Voltaren XR were continued. Evaluation on May 18, 2015, revealed continued pain as noted. He rated his pain without medications at 7 on a 1-10 scale with 10 being the worst and at 1-2 with medications on a scale of 1-10 with 10 being the worst. It was noted toxicology screen on April 20, 2015, revealed findings consistent with expectations. Evaluation on June 15, 2015, revealed continued pain as noted. He rated his pain at 7 on a 1-10 scale without medications and at 1 on a 1-10 scale with the use of medications. It was noted straight leg test on the right was positive and there was limited active range of motion. He reported being able to continue to engage in activities of daily living and to work. He reported Ambien helped him sleep. There was no indication of how many hours of sleep he obtained before starting Ambien and no indications of how many hours of sleep were obtained

with the use of Ambien. A trial of Silenor was prescribed secondary to the drug being noted as non-habit forming. Norco 10/325mg #60, Silenor 6mg #30 and Voltaren XR 100mg #30 were requested.

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

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

**Voltaren XR 100mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter, under Diclofenac sodium (Voltaren®, Voltaren-XR®).

**Decision rationale:** The patient presents with low back pain. The request is for Voltaren XR 100mg #30. Physical examination to the lumbar spine on 06/15/15 revealed tenderness to palpation over the right paraspinal muscles. Range of motion was noted to be limited. Straight leg raising test was positive on the right. Per 05/18/15 progress report, patient's diagnosis include sprain of lumbar region, degeneration of lumbar or lumbosacral intervertebral disc, sciatica, lumbar radicular pain, lumbar spinal stenosis, lumbar disc herniation L4-5 and L5-S1, low back pain, and chronic pain syndrome. Patient's medications, per 04/20/15 progress report include Diclofenac, Norco, Tramadol, Cyclobenzaprine, Omeprazole, and Ambien. Patient's work status is modified duties. MTUS Chronic Pain Medical Treatment Guidelines, page 67 and 68, NSAIDs (non-steroidal anti-inflammatory drugs) section under Back Pain - Chronic Low Back Pain states: "Recommended as an option for short-term symptomatic relief." ODG-TWC, Pain (Chronic) Chapter, under Diclofenac sodium (Voltaren, Voltaren-XR) states: "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. For a patient who has a 5% to 10% risk of having a heart attack that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. (McGettigan, 2011)" The treater has not discussed this request; no RFA was provided either. Review of the medical records indicates that the patient has been utilizing since at least 02/24/15. However, the treater does not document any improvement in function or reduction in pain due to its use. MTUS guidelines, page 60 requires recording of pain and function when medications are used for chronic pain. Furthermore, ODG supports the use of this medication only if other NSAIDs have failed and the patient has a low risk profile. The request is not medically necessary.

**Silenor 6mg #30: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/doxepin.html>.

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

**Decision rationale:** The patient presents with low back pain. The request is for Silenor 6mg #30. Physical examination to the lumbar spine on 06/15/15 revealed tenderness to palpation over the right paraspinal muscles. Range of motion was noted to be limited. Straight leg raising test was positive on the right. Per 05/18/15 progress report, patient's diagnosis include sprain of lumbar region, degeneration of lumbar or lumbosacral intervertebral disc, sciatica, lumbar radicular pain, lumbar spinal stenosis, lumbar disc herniation L4-5 and L5-S1, low back pain, and chronic pain syndrome. Patient's medications, per 04/20/15 progress report include Diclofenac, Norco, Tramadol, Cyclobenzaprine, Omeprazole, and Ambien. Patient's work status is modified duties. MTUS Chronic Pain Medical Treatment Guidelines, page 15, Specific Antidepressants section states: "Tricyclic antidepressants are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem. Caution is required because tricyclics have a low threshold for toxicity, and tricyclic antidepressant overdose is a significant cause of fatal drug poisoning due to their cardiovascular and neurological effects. Tricyclic antidepressants have been shown in both a meta-analysis (McQuay, 1996) and a systematic review (Collins, 2000) to be effective, and are considered a first-line treatment for neuropathic pain." MTUS Chronic Pain Medical Treatment Guidelines, page 122, Tricyclics section states: "Recommended Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated." Treater has not specifically discussed this request and no RFA was provided. Review of medical records provided does not indicate prior use of this Silenor. The patient has a diagnosis of lumbar radicular pain and the sleep medication Ambien has been included in his prescription. Guidelines recommend anti-depressants for patients with chronic neuropathic/non-neuropathic pain and insomnia. This appears to be the initial trial prescription of Silenor. Since this is the initial prescription, treater has not had an opportunity to document medication efficacy. This request appears reasonable and in accordance with guidelines. Therefore, the request is medically necessary.

**Norco 10/325mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Medications for chronic pain, Opioids for chronic pain.

**Decision rationale:** The patient presents with low back pain. The request is for Norco 10/325mg #60. Physical examination to the lumbar spine on 06/15/15 revealed tenderness to palpation over the right paraspinal muscles. Range of motion was noted to be limited. Straight leg raising test was positive on the right. Per 05/18/15 progress report, patient's diagnosis include sprain of lumbar region, degeneration of lumbar or lumbosacral intervertebral disc, sciatica, lumbar radicular pain, lumbar spinal stenosis, lumbar disc herniation L4-5 and L5-S1, low back pain,

and chronic pain syndrome. Patient's medications, per 04/20/15 progress report include Diclofenac, Norco, Tramadol, Cyclobenzaprine, Omeprazole, and Ambien. Patient's work status is modified duties. MTUS, Criteria for use of Opioids Section, pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, Criteria for use of Opioids Section, page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS, Criteria for use of Opioids Section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, Medications for chronic pain Section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." MTUS, Opioids for chronic pain Section, pages 80 and 81 states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." MTUS, p90 states, "Hydrocodone has a recommended maximum dose of 60mg/24hrs." The treater has not specifically discussed this request; no RFA was provided either. The utilization review letter dated 08/20/15 has modified the request from #60 to #30, recommending tapering. Review of the medical records provided indicates that the patient has been utilizing Norco since at least 02/24/15. However, there are no discussions in regards to Norco's impact on the patient's pain and function. No ADL's are discussed showing specific functional improvement. While UDS test results and CURES are current and consistent with patient's medications, there are no discussions on adverse effect and other measures of aberrant behavior. Outcome measures are not discussed and no validated instruments are used showing functional improvement as required by MTUS. Furthermore, MTUS does not support long-term use of opiates for chronic low back pain and on-going use of opiates does not appear appropriate for this patient's condition. The request is not medically necessary.