

<b>Case Number:</b>	CM15-0120728		
<b>Date Assigned:</b>	07/01/2015	<b>Date of Injury:</b>	05/16/2010
<b>Decision Date:</b>	09/01/2015	<b>UR Denial Date:</b>	05/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/22/2015

### 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 51 year old male, who sustained an industrial injury on 5/16/2010. The mechanism of injury is unclear. The injured worker was diagnosed as having prior lumbar laminectomy and discectomy, herniated disc of the lumbar spine right sided, right sided radiculopathy, spondylosis/spondylolisthesis, status post anterior posterior lumbar interbody fusion at L5-S1 with pedicle screw fixation and intradiscal device. Treatment to date has included medications, CT scan of the lumbar spine (4/23/2015), magnetic resonance imaging of the lumbar spine (2/18/2015). The request is for prospective usage of Zanaflex, Lyrica, Norco, Tramadol, and Motrin. The records indicated he has been utilizing Norco, Zanaflex, Lyrica, Motrin, and Nexium since at least November 2014. On 11/24/2014, he complained of low back pain with radiation down the lower extremities. He is reported to not be working. He is currently utilizing Norco 3-4 times per day, Zanaflex twice per day, Motrin once per day, and Lyrica once per day. He is reported to have tried to wean down the Norco to 3 per day but his pain increased. He reported a pain level of 5/10 with medications and 10/10 without medications. He noted improvement with activities of daily living as well as increased ability to sit, stand, and walk. He indicated that with medications he can walk over 400 yards, and without medications he can barely walk 200 yards. Physical findings revealed tenderness, muscle spasms and myofascial trigger points in the low back. The treatment plan included: Norco, Zanaflex, Lyrica, Motrin, urine drug screen and re-evaluation in 4 weeks. All other provided medical records are dated after the UR report. On 12/22/2014, the provider noted he was attempting to transition the injured worker from Norco to Tramadol, as Norco was felt to be insufficient for pain control. He

is noted to have failed to keep his scheduled appointment on 3/18/2015, and 5/1/2015. On 2/18/2015, he complained of low back pain rated 5/10 with medication and 10/10 without medication. On 2/19/2015, he received an initial neurosurgical consultation. On 4/3/2015, he complained of low back pain rated 5/10 with medications and 10/10 without medications. He is noted to have had consistent urine drug screens and never demonstrating aberrant drug behaviors. On 5/6/2015, he complained of low back pain with radiation into the lower extremities, worse on the right. He rated his pain 10/10. He is not working at this time. He reported having increased spasms in the low back and legs over the last 2 weeks. He takes 2 Norco tablets per day for pain, and 2 Tramadol tablets per day for moderate breakthrough pain. He is reported to be using Zanaflex for muscle spasms, and Motrin for inflammation, as well as, Lyrica for neuropathic pain and Nexium for the gastrointestinal side effects from his medication. The provider noted functional improvement and pain improvement is noted with current medication regimen. Pain is rated as 5-7/10 with medications and 10/10 without medications. He reported improved ability to do activities of daily living, sit, stand walk, and sleep. Physical findings revealed tenderness, muscle spasms, and myofascial trigger points in the low back region, and testing revealed a positive seated straight leg raise bilaterally. The treatment plan included: treatment with a neurosurgeon, Norco, Motrin, Tramadol, Lyrica, Zanaflex, opioid treatment agreement review, and urine drug screening.

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

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

**Lyrica 75mg #60 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 16-22.

**Decision rationale:** According to the CA MTUS guidelines, Lyrica (Pregabalin) is an anti-epilepsy drug (AED), also referred to as anti-convulsants. AEDs are recommended for neuropathic pain (pain due to nerve damage). Pregabalin has been documented to be effective in treatment of diabetic neuropathy and post-herpetic neuralgia. Lyrica has FDA approval for both indications, and is considered first-line treatment for both. In 2007, the FDA gave approval for the use of Pregabalin as the first approved treatment for fibromyalgia. The CA MTUS states "a good response to the use of AEDs has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the trigger for: a switch to a different first line agent, combination therapy if treatment with a single drug agent fails". Ongoing treatment should reflect documentation of pain relief and functional improvement, as well as, side effects of the anti-epilepsy drug. In this case, the injured worker reported radiating pain into the lower extremities. However, the documentation indicated in his most recent assessment that he had had increased pain with increased muscle spasms in the low back and legs. The documentation indicated that he attained pain improvement from 10/10 to 5-7/10 with the use of medications; however it does not indicate the relation between pain relief and Lyrica.

The documentation also does not demonstrate what functional gains had been attained with the use of Lyrica, or any noted side effects with its use. In addition the requested Lyrica 75 mg #60 with 2 refills, does not indicate the frequency or dosing for this medication. Therefore, the requested Lyrica 75 mg #60 with 2 refills is not medically necessary.

**Norco 10/325mg #60:** 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 the treatment of chronic pain Page(s): 91-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids.

**Decision rationale:** According to the CA MTUS and ODG, Norco 10/325mg (Hydrocodone/Acetaminophen) is a short-acting opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. 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 insufficient evidence that the opioids were prescribed according to the CA MTUS guidelines, which recommend prescribing according to function, with specific functional goals, return to work, random drug testing, an opioid contract, and documentation of a prior failure of non-opioid therapy. In addition, the MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no documentation of significant pain relief or increased function from the opioids used to date. Medical necessity of the requested medication 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.

**Tramadol 50mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-96.

**Decision rationale:** According to the California MTUS, Tramadol (Ultram) is a synthetic opioid which affects the central nervous system and is indicated for the treatment of moderate to severe pain. Per CA 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 opioid, and the duration of pain relief. According to the medical records, there has been no documentation of the medication's analgesic effectiveness or functional improvement, and no clear documentation that the patient

has responded to ongoing opioid therapy. Medical necessity of the requested medication has not been established. Of note, discontinuation of an opioid analgesic requires a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Zanaflex 4mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), muscle relaxants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine (Zanaflex); Muscle relaxants (for pain) Page(s): 63-66.

**Decision rationale:** Zanaflex (Tizanidine) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. It is indicated for the treatment of chronic myofascial pain and considered an adjunct treatment for fibromyalgia. According to CA MTUS Guidelines, muscle relaxants have not been considered any more effective than non-steroidal anti-inflammatory drugs (NSAIDs) for pain or overall improvement. There is no additional benefit shown in combination with NSAIDs. In addition, sedation is the most commonly reported adverse effect of muscle relaxant medications. In this case, the patient has no reported lumbar spasm on physical exam. Also, the guideline criteria do not support the long-term use of muscle relaxants. Medical necessity for the requested medication has not been established. Zanaflex is not medically necessary.

**Motrin 800mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) NSAIDs.

**Decision rationale:** Motrin (Ibuprofen) is a non-steroidal anti-inflammatory drug (NSAID). Oral NSAIDs are recommended for the treatment of chronic pain and control of inflammation as a second-line therapy after acetaminophen. ODG states that NSAIDs are recommended for acute pain, osteoarthritis and acute exacerbations of chronic pain. There is no evidence of long-term effectiveness for pain or function. There is inconsistent evidence for the use of NSAIDs to treat long-term neuropathic pain. Guidelines recommended that the lowest effective dose be used for the shortest duration of time consistent with treatment goals. In this case, the patient has been on previous long-term NSAIDs without any documentation of significant improvement. Medical necessity of the requested medication, Motrin 800mg, has not been established. The request for this medication is not medically necessary.