

<b>Case Number:</b>	CM15-0080770		
<b>Date Assigned:</b>	05/01/2015	<b>Date of Injury:</b>	11/29/2002
<b>Decision Date:</b>	07/03/2015	<b>UR Denial Date:</b>	04/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/27/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive Medicine

### 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 female who sustained an industrial injury on 11/29/2002. Current diagnoses include cervical degenerative disc disease and radiculopathy. Previous treatments included medication management, cervical epidural injection, activity modification, heat/ice, and home exercise. Previous diagnostic studies include a MRI of the cervical spine and urine drug screen. Report dated 04/15/2015 noted that the injured worker presented with complaints that included neck pain and bilateral extremity pain. Pain level was 4 out of 10 on the visual analog scale (VAS) with medications. Physical examination was positive for abnormal findings. The treatment plan included continue with conservative measures with use of heat, ice, rest, and gentle stretching and exercise, requests for medications, follow up in one month, and cervical epidural is pending. Disputed treatments include Oxycodone oral concentrate, Trazodone, Celebrex, Lyrica, and Skelaxin.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**5 Oxycodone 20 mg/ml oral concentrate, 1.5 ml po q6h #180 ml. 30 day fill; 0 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological basis of Therapeutics and Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) and Pain, Opioids.

**Decision rationale:** Oxycodone is the generic version of Oxycotin, which is a pure opioid agonist. ODG does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has far exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, increased level of function, or improved quality of life. In addition, the treating physician does not provide an objective rationale explaining the need for an oral concentrate form of this medication, the patient is prescribed other medications in tablet form. As such the request for 5 Oxycodone 20 mg/ml oral concentrate, 1.5 ml po q6h #180 ml. 30 day fill; 0 refills is not medically necessary.

**Trazodone 150 mg tabs #30; 1 tab po qhs 30 day fill; 0 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological basis of Therapeutics and Official Disability Guidelines (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress, Trazodone.

**Decision rationale:** Regarding Trazodone, the above cited guidelines say: "Recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. See also Insomnia treatment, where it says there is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. The current recommendation is to utilize a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. Also worth noting, there has been no dose-finding study performed to assess the dose of trazodone for insomnia in non-depressed patients. Other pharmacologic therapies should be recommended for primary insomnia before considering trazodone, especially if the insomnia is not accompanied by comorbid depression or recurrent treatment failure. There is no clear-cut evidence to recommend trazodone first line to treat primary insomnia." The patient has a history of depression and insomnia, however, the treating physician has not provided documentation of objective

functional improvement or subjective reports of improvement of symptoms with the use of this medication. As such, the request for Trazodone 150 mg tabs #30; 1 tab po qhs 30 day fill; 0 refills is not medically necessary.

**Celebrex 200 mg tabs #30; 1 tab po bid; 30 day fill; 0 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological basis of Therapeutics and Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines Anti-inflammatory medications, Celebrex, NSAIDs Page(s): 22, 30, 70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Anti-inflammatory medications are the traditional first line treatment for pain, but COX-2 inhibitors (Celebrex) should be considered if the patient has risk of GI complications, according to MTUS. The medical documentation provided does not indicate a reason for the patient to be considered high risk for GI complications. Risk factors for GI bleeding according to ODG include: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose or multiple NSAID (e.g., NSAID + low-dose ASA). The medical records do not indicate that the patient is undergoing treatment for any of the FDA approved uses such as osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea. As such, the request for Celebrex 200 mg tabs #30; 1 tab po bid; 30 day fill; 0 refills is not medically necessary.

**Lyrica 200 mg tabs #90; 1 tab po tid; 30 day fill; 0 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological basis of Therapeutics and Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), page 16-17, Pregabalin (Lyrica) Page(s): 99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anti-epilepsy drugs (AEDs) for pain.

**Decision rationale:** MTUS and ODG state that "Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references." MTUS additionally comments "Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants. Recommended for neuropathic pain (pain due to nerve damage). 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 the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use." The patient appears to have established neuropathic pain for which Lyrica is an appropriate medication. The medical records provided do not detail any objective improvement over the last several months. Overall, pain improvement has not been documented. Given the lack of subjective and objective improvement, the request for Lyrica 200 mg tabs #90; 1 tab po tid; 30 day fill; 0 refills is not medically necessary.

**Skelaxin 800 mg tabs #90; 1 tab po tid; 30 day fill, 0 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological basis of Therapeutics and Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasmodics Page(s): 64-66.

**Decision rationale:** Additionally MTUS writes "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence." MTUS states regarding Skelaxin (metaxalone), "Recommended with caution as a second-line option for short-term pain relief in patients with chronic LBP. Metaxalone (marketed by [REDACTED] under the brand name Skelaxin) is a muscle relaxant that is reported to be relatively non-sedating." Medical records do not indicate the failure of first line treatments. The requested Skelaxin 800 mg tabs #90; 1 tab po tid; 30 day fill, 0 refills would be more than for the recommended 2-3 week short term treatment period, and so it is not medically necessary.