

Case Number:	CM14-0200004		
Date Assigned:	12/10/2014	Date of Injury:	06/25/2002
Decision Date:	02/05/2015	UR Denial Date:	11/06/2014
Priority:	Standard	Application Received:	12/01/2014

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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This patient is a 59 year old employee with date of injury of 6/5/2002. Medical records indicate the patient is undergoing treatment for lumbar back pain, myofascial pain and degenerative disk disease. Subjective complaints include low back pain and right leg pain that has been "stable" for years. In the last two months, he has described many episodes of increased pain. Lifting and bending exacerbate the pain and the pain limits his activity and causes social isolation. Objective findings include slow, antalgic gait and walks with a cane. Exam to the lumbar spine reveals tender bilateral paraspinal muscles, lumbosacral musculature and no significant axial tenderness. He has significant muscle spasm through the lumbosacral musculature and his lumbar range of motion includes painful extension, rotation and flexion. Treatment has consisted of back brace, Norco, MS Contin, Cymbalta, Baclofen, Lyrica, Lunesta and right S1 epidural steroid injection. The utilization review determination was rendered on 11/6/14 recommending non-certification of Norco 10/325MG #240; MS Contin 60mg, #150; Cymbalta 60mg, # 60; Baclofen 10mg #120; Lyrica 225mg #60 and Lunesta 3mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription of Norco 10/325MG #240: Upheld

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

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), Opioids.

Decision rationale: Official Disability Guidelines (ODG) does not recommend the use of opioids for low back "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. California 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, pain relief, increased level of function, or improved quality of life. In addition, the patient has been on Norco since at least 2012 which has exceeded the guideline recommended treatment length for opioid usage. As such, the request for 1 Prescription of Norco 10/325MG #240 is not medically necessary.

1 Prescription of MS Contin 60mg, #150: Upheld

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

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), Opioids.

Decision rationale: MS Contin is a pure opioid agonist. Official Disability Guidelines (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 exceeded the 2 week recommended treatment length for opioid usage. California 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, pain relief, increased level of function, or improved quality of life. In addition, the patient has been on MS Contin and other opioids since at least 2012 which has exceeded the guideline recommended treatment length for opioid usage. As such the request for MS Contin 60MG # 150 is not medically necessary.

1 Prescription of Cymbalta 60mg, # 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Weaning of Medications (Antidepressants).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain interventions and Treatments Page(s): 15-16.

Decision rationale: California MTUS state regarding antidepressants for pain, "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur." The treating physician does not indicate failure of first-line agents and does not indicate how a first line agent is ineffective, poorly tolerated, or contraindicated. MTUS states regarding Cymbalta: "Selective serotonin and norepinephrine reuptake inhibitors (SNRIs): Duloxetine (Cymbalta): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects: CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs.2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%). Trial period: Some relief may occur in first two weeks; full benefit may not occur until six weeks. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation." Medical records do not substantiate anxiety, depression, diabetic neuropathy, and/or fibromyalgia, which are the only FDA indicated uses of Cymbalta. As such, the request for Cymbalta 60mg #60 is not medically necessary.

1 Prescription of Baclofen 10mg #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Mental Illness & Stress

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-64.

Decision rationale: Baclofen is classified as a muscle relaxant. California MTUS states "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. 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." Additionally, MTUS states "Baclofen (Lioresal , generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)." The treating physician has not provided documentation of muscle spasms related to multiple sclerosis or spinal cord injuries. Additionally, the treating

physician has not provided documentation of trials and failures of first line therapies. As such the request for Baclofen 10mg, #120 is not medically necessary.

1 Prescription of Lyrica 225mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs).

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

Decision rationale: California MTUS and Official Disability Guidelines (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 treating physician has not documented pain relief and improvement in function while taking Lyrica. In addition, the patient has been taking Lyrica since January, 2013 and recently reported an increase in pain and decrease in functionality. As such, the request for 1 Prescription of Lyrica 225mg #60 is not medically necessary.

1 Prescription of Lunesta 3mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Mental Illness & Stress

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, insomnia, Mental Illness, Eszopicolone (Lunesta).

Decision rationale: California MTUS is silent specifically regarding eszopicolone (Lunesta), therefore other guidelines were utilized. Official Disability Guidelines (ODG) states regarding Eszopicolone, "Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase." For insomnia ODG recommends that "Pharmacological agents should only be used after careful

evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical records do not indicate patient's sleep hygiene or the need for variance from the guidelines, such as "a) Wake at the same time every day; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping." Medical documents indicate that the patient has been on Eszopicolone since at least 01/2013, far exceeding guidelines. Additionally, medical records do not indicate what components of insomnia has been addressed, treated with conservative measures, and the results of those conservative treatments. As such, the request for 1 Prescription of Lunesta 3mg #30 is not medically necessary.