

<b>Case Number:</b>	CM15-0004446		
<b>Date Assigned:</b>	02/12/2015	<b>Date of Injury:</b>	11/08/1986
<b>Decision Date:</b>	04/06/2015	<b>UR Denial Date:</b>	12/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/08/2015

### 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, New York, Florida

Certification(s)/Specialty: Internal Medicine, Pulmonary Disease, Critical Care 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 58-year-old female who reported an injury on 11/08/1985. The mechanism of injury was unspecified. Relevant diagnoses include post lumbar laminectomy syndrome, lumbar degenerative disc disease, lumbar radiculopathy, chronic back pain and hip bursitis. Past treatments include medications, injections and physical therapy. On 12/11/2014, the injured worker complained of mid back and low back pain, rated 6/10 with medications and 10/10 without medications. The injured worker also indicated while the sleep was poor, however, the activity level has remained the same as the injured worker noted pain flare ups in the low back radiating down the left leg. Injured worker was also indicated to have left foot drop and ambulated with a cane. Relevant medications were noted to include Biotene Oral Balance Gel, Cymbalta 60 mg, Lidoderm 5% patch, Lyrica 150 mg, carisoprodol 350 mg, Celebrex 100 mg, Norco 10/325 mg, Oxycontin 80 mg, Senokot 8.6 mg, Lunesta 3 mg, omeprazole 20 mg, furosemide 40 mg, levothyroxine 25 mcg, metoprolol 50 mg, Provigil 100 mg, simvastatin 40 mg and bupropion 300 mg. The treatment plan included Oxycontin 80mg #252, Lunesta 3mg #25, carisoprodol 350mg #56, Norco 10/325mg #84, Senokot 8.6mg #28, Celebrex 100mg #56, MiraLAX powder 17gm/does #1, omeprazole DR 20mg #28, Biotene Oralbalance Gel #2 with five refills, Cymbalta 60mg #56 with five refills, Lidoderm 5% patch #56 with five refills and Lyrica 150 #84 with five refills for break through pain relief, muscle spasms, mood improvement and neuropathic pain. A Request for Authorization form was submitted on 12/13/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Oxycontin 80mg #252:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines On-going management Page(s): 78.

**Decision rationale:** The request for Oxycontin 80mg #252 is not medically necessary. According to the California MTUS Guidelines, ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug related behaviors. The injured worker was indicated to have been on Oxycontin for an unspecified duration of time. However, there was lack of documentation in regard to monitoring for side effects. Furthermore, guidelines do not support the use of opioids for long term use. A recommendation for a weaning schedule should be implemented based on the injured worker's opioid history. As such, the request is not supported by the evidence based guidelines. Therefore, the request is not medically necessary.

**Lunesta 3mg #25:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The request for Lunesta 3mg #25 is not medically necessary. The Official Disability Guidelines recommend short acting nonbenzodiazepines, as first line medications for insomnia, additionally indicated for the short term treatment of insomnia with difficulty of sleep onset (7 to 10 days). Lunesta is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. The injured worker was indicated to have been on Lunesta for an unspecified duration of time. There was lack of documentation to indicate monitoring for sleep maintenance, to include onset of medication and the duration of sleep with medication use. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.

**Carisoprodol 350mg #56:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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

**Decision rationale:** The request for carisoprodol 350mg #56 is not medically necessary. The California MTUS Guidelines recommend nonsedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Furthermore, the guidelines do not recommend Soma longer than a 2 to 3 week period. The guidelines also state in most low back pain cases, muscle relaxants show no benefit beyond NSAIDs in pain and overall improvement. The efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The injured worker was indicated to have been on carisoprodol for an unspecified duration of time. There was lack of documentation in regard to an acute exacerbation with chronic low back pain. Furthermore, there was lack of documentation of a clear rationale to indicate long term use of Soma as the guidelines do not recommend the use beyond 2 to 3 weeks. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.

**Norco 10/325mg #84:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines On-going management Page(s): 78.

**Decision rationale:** The request for Norco 10/325mg #84 is not medically necessary. According to the California MTUS Guidelines, ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug related behaviors. The injured worker was indicated to have been on Norco for an unspecified duration of time. However, there was lack of documentation in regard to monitoring for side effects. Furthermore, guidelines do not support the use of opioids for long term use. A recommendation for a weaning schedule should be implemented based on the injured worker's opioid history. As such, the request is not supported by the evidence based guidelines. Therefore, the request is not medically necessary.

**Senokot 8.6mg #28:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Initiating Therapy Page(s): 77.

**Decision rationale:** The request for Senokot 8.6mg #28 is not medically necessary. According to the California MTUS Guidelines, prophylactic treatment of constipation should be initiated. The injured worker was indicated to have been on Senokot for an unspecified duration of time. Although the injured worker was noted to have been on opioids there was lack of documentation to indicate gastrointestinal side effects, to include constipation, upon physical examination. As

such, the request is not supported by the evidence based guidelines. Therefore, the request is not medically necessary.

**Celebrex 100mg #56: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 68-69.

**Decision rationale:** The request for Celebrex 100mg #56 is not medically necessary. According to the California MTUS Guidelines, an assessment is needed for patients at risk for gastrointestinal events: (1) age greater than 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/multiple NSAIDs are indicated for Osteoarthritis including knee and hip. In addition, NSIADs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Patients should also have had an initial therapy of Acetaminophen for mild to moderate pain and for the treatment of dyspepsia secondary to NSAID therapy. The injured worker was indicated to have been on Celebrex for an unspecified duration of time. There was lack of documentation to indicate the injured worker had dyspepsia secondary to NSAID therapy; had a concurrent use of ASA, corticosteroids and/or anticoagulants; was using high dose/multiple NSAIDs; was over the age of 65; or had a history of GI bleeding or perforation and peptic ulcers. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.

**Miralax powder 17gm/does #1: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Initiating therapy Page(s): 77.

**Decision rationale:** The request for MiraLAX powder 17gm/does #1 is not medically necessary. According to the California MTUS Guidelines, prophylactic treatment of constipation should be initiated. The injured worker was indicated to have been on MiraLAX for an unspecified duration of time. Although the injured worker was noted to have been on opioids, however, there was lack of documentation to indicate gastrointestinal side effects, to include constipation, upon physical examination. As such, the request is not supported by the evidence based guidelines. Therefore, the request is not medically necessary.

**Omeprazole Dr 20mg #28: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 68-69.

**Decision rationale:** The request for omeprazole DR 20mg #28 is not medically necessary. According to the California MTUS Guidelines, an assessment is needed for patients at risk for gastrointestinal events: (1) age greater than 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/multiple NSAIDs are indicated for Osteoarthritis including knee and hip. In addition, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Patients should also have had an initial therapy of Acetaminophen for mild to moderate pain and for the treatment of dyspepsia secondary to NSAID therapy. The injured worker was indicated to have been on omeprazole for an unspecified duration of time. There was lack of documentation to indicate the injured worker had dyspepsia secondary to NSAID therapy; had a concurrent use of ASA, corticosteroids and/or anticoagulants; was using high dose/multiple NSAIDs; was over the age of 65; or had a history of GI bleeding or perforation and peptic ulcers. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.

**Biotene Oralbalance Gel #2 with five refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation European Journal of Dentistry.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: American Academy of Oral Medicine.

**Decision rationale:** The request for Biotene Oralbalance Gel #2 with five refills is not medically necessary. According to the American Academy of Oral Medicine, there are many over the counter (OTC) products that may aid in moisturizing and lubricating of the oral tissues. These agents are typically available as gels or liquids such as: Biotene Oral Balance Moisturizing Gel & Dry Mouth Liquid, Entertainer's Secret, Moi-Stir, Moist Plus Mouth Moisturizer, Mouth Kote, Oasis Moisturizing Mouth Spray, Saliva Substitute, Salivart Oral Moisturizer, and TheraSpray. The injured worker was indicated to have been on Biotene Oral Balance Gel for an unspecified duration of time. Based on the product being over the counter and other available formulations, the request for Biotene with 5 refills would not be supported by the evidence based guidelines. In addition, the request for refills would not be supported as it does not allow time for reassessment between medications. As such, the request is not medically necessary.

**Cymbalta 60mg #56 with five refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressant Page(s): 13-16.

**Decision rationale:** The request for Cymbalta 60mg #56 with five refills is not medically necessary. According to the California MTUS Guidelines, patients on Antidepressants should have an assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance), should be assessed. Furthermore, the guidelines indicate it is FDA approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. The injured worker was indicated to have been on Cymbalta for an unspecified duration of time. There was lack of documentation in regard to an evaluation with medication use, to include functional, analgesia effects, sleep quality and duration, and a psychological assessment. There was also lack of documentation to indicate the injured worker had depression, anxiety, diabetic neuropathy or fibromyalgia to support its use. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.

**Lidoderm 5% patch #56 with five refills:** 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 request for Lidoderm 5% patch #56 with five refills is not medically necessary. According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Furthermore, it may be used for localized peripheral pain after there has been evidence of a trial of first line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). The injured worker was indicated to have been on Lidoderm patches for an unspecified duration of time. There was lack of documentation to indicate the injured worker had failed a trial of antidepressants and anticonvulsants. In addition, there was also lack of documentation the injured worker has had a trial of first line therapies, to include tricyclics, SNRI antidepressants or AED or antiepileptic drugs, prior to medication use. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.

**Lyrica 150 #84 with five refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines, Chronic Pain Treatment Guidelines Antiepileptic drugs Page(s): 16-19.

**Decision rationale:** The request for Lyrica 150 #84 with five refills is not medically necessary. According to the California MTUS Guidelines, antiepileptics are recommended for diabetic painful neuropathy and postherpetic neuralgia. They also state, a response to the use of AEDs has been defined as a 30% to 50% reduction in pain. There should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. The injured worker was indicated to have been on Lyrica for an unspecified duration of time. There was lack of documentation indicating the injured worker had diabetic painful neuropathy or postherpetic neuralgia. There was also lack of documentation of the positive outcome of at least 30% to 50% reduction in pain, along with improvement of function and monitoring for side effects incurred with use. Based on the above, the request is not supported by the evidence based guidelines. As such, the request is not medically necessary.