

<b>Case Number:</b>	CM15-0034704		
<b>Date Assigned:</b>	03/03/2015	<b>Date of Injury:</b>	01/04/2007
<b>Decision Date:</b>	04/16/2015	<b>UR Denial Date:</b>	02/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/24/2015

### 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 62 year old female, who sustained an industrial injury on 1/04/2007. The diagnoses have included lumbago, thoracic or lumbosacral neuritis or radiculitis, unspecified, and postlaminectomy syndrome, lumbar region. Treatment to date has included surgical and conservative measures. Currently, the injured worker complains of constant low back pain on the left and intermittent leg pain. She also reported headaches. Average pain level was 4/10. She reported poor sleep quality due to pain and reported that Ambien worked well, when she used it, sleeping 4-5 hours interrupted. She was not working. Magnetic resonance imaging of the lumbar spine (5/18/2011) was referenced as showing minimal central canal stenosis and mild bilateral foraminal stenosis at L5-S1 and L4-5, secondary to broad based disc protrusions. Current medications included Ambien CR as needed, Celebrex as needed, Dilaudid as needed, Fentanyl patch, Lyrica as needed, Prilosec as needed, and Zanaflex as needed. Physical exam suggested stable but ongoing symptoms. Limited active range of motion was noted to the lumbar region due to pain. She had facet based and discogenic pain on exam. Treatment plan included medication refills and addition of neuropathic pain cream. On 2/12/2015, Utilization Review (UR) non-certified a request for Dilaudid 2mg #90, non-certified a request for Celebrex 200mg trial, stopping for one week, non-certified a request for Ambien CR 6.25mg #30, non-certified a request for Zanaflex 4mg #60, non-certified a request for Prilosec 20mg #30, non-certified a request for Fentanyl patch 25mcg/hr #10, and non-certified a request for neuropathic pain cream. The UR physician cited MTUS Chronic Pain Medical Treatment Guidelines and Official Disability Guidelines.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Dilaudid 2mg quantity 90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 80.

**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:** In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. When these drugs do not satisfactorily reduce pain, opioids for moderate to severe pain may be added. According to ODG and MTUS, Dilaudid is a long-acting opioid analgesic that is four times more powerful than Morphine. It 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 no documentation of the medication's pain relief effectiveness. There was no documentation of functional improvement from previous usage of Dilaudid, to consider continuation of this medication. Of note, discontinuation of an opiate should include a taper, to avoid withdrawal symptoms. Medical necessity of the requested item has not been established. The requested medication is not medically necessary.

**Celebrex 200mg trial, stopping for one week:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti Inflammatory medications Page(s): 22.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Celebrex Page(s): 30. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Anti-inflammatory Medications.

**Decision rationale:** Celebrex (Celecoxib) is a nonsteroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. Unlike other NSAIDs, Celebrex does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures. Celebrex may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months. In this case, there is no documentation of the medication's pain relief effectiveness or functional improvement as compared to functionality using a non-prescription anti-inflammatory medication. The medical necessity of the requested medication has not been established. The requested medication is not medically necessary.

**Ambien controlled release 6.25mg, quantity 30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Zolpidem.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Insomnia TreatmentPain, Zolpidem (Ambien) (2015).

**Decision rationale:** Ambien (Zolpidem) is a prescription short-acting non-benzodiazepine hypnotic, which is recommended for short-term treatment of insomnia (two to six weeks). Ambien CR is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. Longer-term studies have found Ambien CR to be effective for up to 24 weeks in adults. This can be habit-forming, and may impair function and memory more than opioid analgesics. There is also concern that Ambien may increase pain and depression over the long-term. The treatment of insomnia should be based on the etiology, and pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. In this case, Ambien CR has been used for greater than 6 months. Medical necessity for the requested medication is not established. The requested medication is not medically necessary.

**Zanaflex 4mg quantity 60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants for pain Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants 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 also 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 reports chronic LBP post-injury, and the guideline does not support chronic use of muscle relaxants. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

**Prilosec 20mg quantity 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non Steroidal Anti Inflammatory drugs, gastro intestinal symptoms and cardiovascular risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to the California MTUS (2009), Omeprazole (Prilosec), is proton pump inhibitor (PPI) that is recommended for patients taking NSAIDs, with documented GI distress symptoms, or at risk for gastrointestinal events. GI risk factors include age >65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants, or high dose/multiple NSAIDs. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. In this case, there is no documentation indicating that this patient had any GI symptoms or risk factors. In addition, the request for Celebrex was not found to be medically necessary, which would mean that Prilosec would not appear to be medically necessary for this patient. Medical necessity for Prilosec has not been established. The requested medication is not medically necessary.

**Fentanyl patch 25ugm, 1 patch every 3 days, quantity 10:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 80.

**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 ODG and MTUS, Fentanyl is a long-acting narcotic analgesic, and is in a class of drugs that has a primary indication to relieve symptoms related to pain. These medications are generally classified according to potency and duration of dosage. Fentanyl is the most potent opioid available for use in medical treatment, 50 to 100 times more potent than morphine, and 30 to 50 times more potent than heroin. A Duragesic transdermal patch (Fentanyl transdermal) is indicated for management of persistent chronic pain, which is moderate to severe, requiring continuous, around-the-clock opioid therapy. Duragesic transdermal patches should only be used in patients who are currently on opioid therapy for which tolerance has developed. These are not for use in routine musculoskeletal pain. Patches are worn for a 72-hour period. 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 no documentation of the medication's pain relief effectiveness, functional status, or response to ongoing opioid analgesic therapy. Of note, discontinuation of an opiate should include a taper, to avoid withdrawal symptoms. Medical necessity of the requested item has not been established. The requested medication is not medically necessary.

**Neuropathic Pain cream for trigeminal neuralgia:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, there is no documentation of the active ingredients in the requested neuropathic cream. In addition, there is no documentation of intolerance to other previous oral medications. The medical necessity of the requested unknown topical analgesic has not been established. The requested item is not medically necessary.