

<b>Case Number:</b>	CM13-0032996		
<b>Date Assigned:</b>	12/06/2013	<b>Date of Injury:</b>	08/12/1997
<b>Decision Date:</b>	03/04/2014	<b>UR Denial Date:</b>	09/26/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/08/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, with a subspecialty in Disability Evaluation, and is licensed to practice in California. 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 physician 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.

### 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 patient is a 52-year-old male who delivered furniture for [REDACTED] when on 08/12/1997 he sustained an industrial injury. The patient states that he and another employee were lifting a table out of a truck, when the table fell and hit him in the head causing a twisting motion in his neck. He is status post 2-level ACDF in 1998 and 1-level ACDF in 1999. In the medical report dated 8/8/12, he presents with increasing pain the neck with numbness into the right pectoral muscle. He reports clumsiness of the hands and dropping objects with the right hand. He has noticed weakness with grip strength activity. On physical examination, flexion is 50% of normal and extension is 25% of normal and produces pain. There is moderate tenderness to palpation over the C3 and C6. There is palpable spasm in the paraspinous muscles. Hoffman's sign is present on the left side. Spurling's test provokes dysesthesia pain on the right side of the neck. Motor strength and sensation are intact. EMG/NCV (electromyogram/nerve conduction velocity test) of the bilateral upper extremities was done on 3/4/11 and revealed a normal study, no evidence of cervical radiculopathy. An MRI of the cervical spine was taken on 8/3/12 and showed a complete fusion at C4-C7. There is field distortion secondary to the anterior screw-plate fixation hardware at C4-5 level. There is annular bulging and posterior spondylitic ridging at C3-4, more prominent on the left side. The midline AP canal diameter measures approximately 8.3mm which is stenotic and stable from 7/8/11. There is bilateral foraminal narrowing at C3-4 worse on the right, stable from 7/8/11. There is annular bulging and posterior spondylitic ridging at C7-T1, more prominent on the left side. The midline AP diameter measures approximately 10.7mm which is stenotic and stable from 7/8/11. There is left-sided foraminal narrowing at C7-T1, stable from 7/8/11. There is no cord compression or cervical cord lesions. X-rays of the cervical spine dated 2/9/11 showed no evidence of instability in flexion or extension. Treatments to date include physical therapy, ESI (epidural steroid injection), HEP (home exercise program), and chiropractic treatments.

Requests are made for diskectomy anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctectomy, cervical single interspace; Arthrodesis, anterior interbody technique, including minimal diskectomy, cervical below C2; anterior instrumentation of two to three vertebral segments; application of intervertebral biomechanical device to vertebral defect or interspace.

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

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

**Fentanly Patch 100mcg:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 44 and 47.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines states that Duragesic<sup>®</sup> (fentanyl transdermal system) is not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by [REDACTED] and marketed by [REDACTED] (both subsidiaries of [REDACTED]). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. This patient continues to be in pain despite various pain management regimen. The request for a Fentanly Patch 100mcg is medically necessary and appropriate.

**Norco 10-325 mg:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Page(s): 80.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines further stated that opioids are indicated for moderate to moderately severe pain and should be continued if pain and functional improvement is documented. Specifically, ongoing management should include documentation of relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. This should include specific notations at each visit of a pain scale and specific functional improvements. The patient has a history of chronic pain. In the records reviewed, there is no objective documentation of significant functional improvement from the use of this medication. This medication cannot be abruptly discontinued, since the guideline stipulates that ongoing use of opiate medication may

be recommended with documented pain relief, an increase in functional improvement, a return to work and evidence of proper use of the medications. Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. When discontinuing opiate pain medication a slow taper is recommended to wean the patient. The request for Norco 10-325 mg, every six hours as needed is medically necessary and appropriate.

**Lyrica 150mg every day:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 19-20.

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

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines, Lyrica which is an Anti-epilepsy drug (AED) are also referred to as anti-convulsants are recommended for neuropathic pain (pain due to nerve damage. (Gilron, 2006) (Wolfe, 2004) (Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007) There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). The request for Lyrica 150mg every day is medically necessary and appropriate.

**Ambien 10mg:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medline Plus Guidelines

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines are mute on Zolpidem also known as Ambien. According to Medline Plus, Zolpidem is used to treat insomnia (difficulty falling asleep or staying asleep) and it belongs to a class of medications called sedative-hypnotics. It works by slowing activity in the brain to allow sleep. Zolpidem should normally be taken for short periods of time (less than two weeks). If zolpidem is taken for two weeks or longer, it may not help a patient sleep as well as it did when the patient first began to take the medication. The request for Ambien 10mg is not medically necessary or appropriate.

**Tramadol HCL ER 100, one tablet three times daily:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93-94.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 84.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines says that Tramadol (Ultram) is classified as a small class of synthetic opioids, with opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine as a Central acting analgesics. This class of synthetic opioids have been reported to be effective in managing neuropathic pain, with side effects similar to traditional opioids. "Opioids efficacy is limited to short term pain relief, and long term efficacy is unclear". Failure to respond to a time-limited course of opioids has led to suggestion of reassessment and consideration of alternative therapy. A recent Cochrane review found that Ultram decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) . Short-term use: recommended on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/acetaminophen, hydrocodone and codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (oxycodone, hydromorphone, fentanyl, morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). (Stitik, 2006) (Avouac, 2007) (Zhang, 2008). Opioids are not recommended as a first line therapy for osteoarthritis, and there is no documentation that the first line therapy has failed. The patient is already on long acting fentanyl patch for chronic pain. No medical rationale was provided to substantiate the concurrent use of these two opioids. Besides, the guideline recommended the use of Tramadol on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. There is no documentation of failure of the first line pain therapy. The request for Tramadol HCL ER 100, one tablet three times daily, is not medically necessary or appropriate.

**Ibuprofen 600mg three times daily:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
Page(s): 72.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID (non-steroid anti-inflammatory drug).

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines , NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain,

and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Prescription of Naproxen 550mg #120 for this diabetic patient is not medically necessary because of the adverse effects profile especially in high risk diabetic patients. A safer alternative such as acetaminophen is more appropriate. According to the above guidelines, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain long term use is not recommended. There is no evidence of long-term effectiveness for pain or function. The request for Ibuprofen 600mg three times daily is not medically necessary or appropriate.