

Case Number:	CM15-0029390		
Date Assigned:	02/23/2015	Date of Injury:	07/19/2006
Decision Date:	04/06/2015	UR Denial Date:	02/11/2015
Priority:	Standard	Application Received:	02/18/2015

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

Certification(s)/Specialty: Family Practice

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 54year old male injured worker suffered and industrial injury on 7/19/2006. The diagnoses were major depressive disorder, complex regional pain syndrome. Left middle finger amputation and left ring finger amputation with severe neuropathic phantom pain. The diagnostic studies were left shoulder magnetic resonance imaging. The treatments were medication. The treating provider reported neck pain that radiated down the left upper extremity. The low back pain radiated down the left lower extremity. The upper extremity pain in the left shoulder hand and arm was accompanied by weakness and numbness. The pain is rated 5/10 to 8/10. The Utilization Review Determination on 2/11/2015 non-certified: 1. Norco 5/325 mg #90, MTUS. 2. Fentanyl 12mcg /hr patch #10, MTUS. 3. Lidocaine HCL 2% jelly, MTUS. 4. Duloxetine HCl DR 60 mg #60, MTUS. 5. Naloxone Hcl 0.4mg /0.4ml Evizo 1ml prefilled syringeX2, dispense #1 emergency kit, MTUS, ACOEM, ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 5/325 mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 76-78, 80.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids including Norco. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an 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. There should be evidence of documentation of the "4 A's for Ongoing Monitoring." These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 A's for Ongoing Monitoring." The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Norco is not considered as medically necessary. In the Utilization Review Process, the request for Norco was modified to allow for weaning. This action is consistent with the above cited guidelines.

Fentanyl 12mcg /hr patch #10: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
Page(s): 47, 78, 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 76-78, 80.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids including Fentanyl. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an 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. There should be evidence of documentation of the "4 A's for Ongoing Monitoring." These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 A's for Ongoing Monitoring." The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Fentanyl is not considered as medically necessary. In the Utilization Review process the request for Fentanyl was modified to allow for weaning. This action is consistent with the above cited guidelines.

Lidocaine HCL 2% jelly: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics such as lidocaine as a treatment modality. These guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines comment on the use of lidocaine. They state the following: Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle

pain. The results showed there was no superiority over placebo. In this case there is insufficient documentation in support of the use of lidocaine jelly. Specifically, there is insufficient documentation that the patient has undergone an adequate trial of a first-line agent such as a tricyclic antidepressant or an anticonvulsant drug. For this reason, lidocaine jelly is not considered as medically necessary.

Duloxetine Hcl DR 60 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-15.

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of antidepressants such as Duloxetine for the treatment of chronic pain. These guidelines state that antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclics (such as Amitriptyline) are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor (SNRI). The MTUS guidelines state the following regarding this medication: 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. No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. In this case, the records do not indicate that the patient has received an adequate trial of a first-line agent such as a tricyclic antidepressant. The MTUS Guidelines do not provide high-quality evidence for the use of Duloxetine as a first-line agent. For these reasons, Duloxetine is not considered as medically necessary.

Naloxone Hcl 0.4mg /0.4ml Evizo 1ml prefilled syringeX2, dispense #1 emergency kit:
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 chapter. ACOEM, Chapter 5, page 79.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids; Dealing with Misuse and Addiction Page(s): 27, 84-85.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the methods to address opioid misuse and addiction. This section of the MTUS Guidelines is

relevant to this issue as Naloxone is used to reverse the effects of an opioid overdose (Page 27). The MTUS guidelines recommend that, if there are active signs of misuse, these concerns should be addressed immediately with the patient. If there are active signs of relapse to addiction, or new-onset addiction, these patients should be referred to an addictionologist immediately. It has been suggested that most chronic pain problems will not resolve while there is active and ongoing alcohol, illicit drug, or prescription drug abuse. Many physicians will allow one "slip" from a medication contract without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations. If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion, it has been suggested that a patient show evidence of consultation with a physician trained in addiction treatment for assessment of the situation and possible detoxification. It is also suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances. (Weaver, 2002) When less serious warning signs arise, the following have been recommended (after making sure that there is no change in the patient's condition that has introduced a need for additional treatment): (a) Initiate closer monitoring with more frequent visits; (b) Consider limitations in the amount of medication prescribed at any one time; & (c) Re-review the clinic policy on controlled substance use and the medication contract. In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to California physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code section 2241.5. In this case, given that Naloxone is being recommended as an emergency treatment for an opioid overdose, it would be expected that the records reflect immediate actions as cited above be taken. There is insufficient documentation in the medical records that these actions to address misuse and addiction of opioids have been addressed. Therefore, for this reason, Naloxone Hcl 0.4mg/0.4 ml Evizo prefilled syringe X 2, dispense #1, is not considered as medically necessary.