

Case Number:	CM15-0131942		
Date Assigned:	07/20/2015	Date of Injury:	06/01/2011
Decision Date:	08/26/2015	UR Denial Date:	06/17/2015
Priority:	Standard	Application Received:	07/08/2015

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, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 34-year-old male who sustained an industrial injury on June 1, 2011. He has reported pain in the neck, shoulders, and upper extremities and has been diagnosed with 4-limb complex regional pain syndrome. Treatment has included medication, injections, and conservative measures. There is little end range pain from rotation of the cervical spine, but tenderness was better, including the neck and shoulders. There was tenderness with right shoulder range of motion. There is less tenderness to palpation about the hip girdles. The treatment request included medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta 75mg #240: 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): 78.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for 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. These domains have been summarized as the "4A's" (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." The MTUS is silent on the use of Nucynta specifically. With regard to tapentadol (Nucynta), the ODG states: "Recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the "4A's" (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Per progress report dated 5/13/15 it was noted Review of the available medical records reveals no documentation to support the medical necessity of Nucynta nor any documentation addressing the '4A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Per progress report dated 5/13/15, it was noted that with the current medication regimen, the treating physician has been successful in not going backward on potent opioid agonists that have induced tolerance and addiction and withdrawal in this patient. "These particular drugs have not been doing that, and consistently, his pain scores throughout my review of this chart demonstrate substantial improvements with these medications, which I believe warrants their continuation." Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 4/10/15 was positive for nucynta and negative for buprenorphine. CURES report was available, however, it was outdated and indicated that in 2013 the injured worker was prescribed opiates from multiple physicians. Absent appropriate UDS, medical necessity cannot be affirmed. It should be noted that the UR physician has certified a modification of the request to allow for submission of appropriate documentation.

Clonidine 0.01mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRPS treatment, Clonidine Intrathecal Page(s): 34-35, 38.

Decision rationale: California MTUS Guidelines indicate clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. Clonidine is a direct-acting, adrenergic agonist historically prescribed as an antihypertensive agent, but has also found new uses including treatment of some types of neuropathic pain. For the treatment of CRPS, the MTUS states: Stimulus-independent pain: The use of antidepressants, anticonvulsants, and opioids has been primarily extrapolated based on use for other neuropathic pain disorders. (See Antidepressants for chronic pain; Anticonvulsants for chronic pain; & Opioids for neuropathic pain.) Mexiletine, lidocaine patches and capsaicin are used but efficacy is not convincing. For central inhibition opiates, gabapentin, TCAs, GABA-enhancing drugs, and clonidine may be useful. The documentation submitted for review indicates that the injured worker has been using this medication since 2013 for CRPS and opiate withdrawal symptoms. Since it has been in use for opiate withdrawal since 2013, it is no longer medically indicated. The request is not medically necessary.

Clinoril 200mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68.

Decision rationale: With regard to the use of NSAIDs for chronic low back pain, the MTUS CPMTG states "Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another." "Low back pain (chronic): Both acetaminophen and NSAIDs have been recommended as first line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-by-case basis based on weighing efficacy vs. side effect profile." The documentation submitted for review makes no mention regarding the use of this medication. It was noted that the injured worker was treated with ibuprofen and acetaminophen in 2013. There was rationale provided as to why treatment with ibuprofen or naproxen was not sufficient. The request is not medically necessary.

Butrans 20mcg #4: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine Page(s): 26-27, 78.

Decision rationale: With regard to Buprenorphine, the MTUS CPMTG states: "recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction (see below for specific recommendations). A schedule-III controlled substance, buprenorphine is a partial agonist at the mu-receptor (the classic morphine receptor) and an antagonist at the kappa-receptor (the receptor that is thought to produce alterations in the perception of pain, including emotional response). In recent years, buprenorphine has been introduced in most European countries as a transdermal formulation ("patch") for the treatment of chronic pain. Proposed advantages in terms of pain control include the following: (1) No analgesic ceiling; (2) A good safety profile (especially in regard to respiratory depression); (3) Decreased abuse potential; (4) Ability to suppress opioid withdrawal; & (5) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor)." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the "4A's" (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of Butrans or any documentation addressing the '4A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Per progress report dated 5/13/15, it was noted that with the current medication regimen, the treating physician has been successful in not going backward on potent opioid agonists that have induced tolerance and addiction and withdrawal in this patient. "These particular drugs have not been doing that, and consistently, his pain scores throughout my review of this chart demonstrate substantial improvements with these medications, which I believe warrants their continuation." Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 4/10/15 was positive for Nucynta and negative for buprenorphine. CURES report was available, however, it was outdated and indicated that in 2013 the injured worker was prescribed opiates from multiple physicians. Absent appropriate UDS, medical necessity cannot be affirmed. It should be noted that the UR physician has certified a modification of the request for the purpose of weaning.