

Case Number:	CM13-0068075		
Date Assigned:	01/15/2014	Date of Injury:	02/13/2002
Decision Date:	06/06/2014	UR Denial Date:	11/15/2013
Priority:	Standard	Application Received:	12/19/2013

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. The expert reviewer is Board Certified in Occupational Medicine 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 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 an employee of [REDACTED] and has submitted a claim for chronic pain syndrome, lumbosacral spondylosis, and failed back syndrome associated with an industrial injury date of February 13, 2002. The treatment to date has included six (6) unspecified back surgeries, arthroscopic right knee surgery on 2012, physical therapy, and medications such as Amitiza, Bentyl, Chantix, chondroitin sulfate + glucosamine + MSM, ibuprofen, MS Contin, phenobarbital, Robinul Forte, Tenoretic, trazodone, Zantac, Fioricet, Nucynta, tiagebine, Subutex, and Tofranil. The medical records from 2012 to 2013 were reviewed. The most recent progress report available was dated January 10, 2013. It showed that the patient complained of low back pain radiating to both legs associated with numbness of the left leg. It was described as shooting pain at both feet. Pain was aggravated by bending; and alleviated by sitting and lying on the bed. The patient likewise complained of sharp, localized pain over the neck and upper back when lifting heavy objects or engaging in strenuous activities. The physical examination showed tenderness over the lumbosacral spine. No other objective findings were noted. The utilization review from November 15, 2013 denied the requests for Fiorcet one to two (1-2) tabs every four (4) hours as needed, max 5#150; lidocaine/prilocaine 2.5%/2.5% topical cream applied to knee twice a day to four times a day; Nucynta 100 mg one to two (1-2) tabs every six (6) hours as needed for pain, #120; Nucynta ER 200 mg two (2) tabs every twelve (12) hours for pain control, #120; Subutex 8 mg, #60 one (1) SL four times a day; Tiagebine 4 mg, #180 two (2) tabs three times a day; trazodone 150 mg #270 3 three times a day; Voltaren topical gel 1% four times a day for pain; and ranitidine 300 mg #90 one (1) daily. The reasons for denial were not made available.

IMR ISSUES, DECISIONS AND RATIONALES

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

FIORCET 1-2 TABS EVERY 4 HRS AS NEEDED; MAX 5 #150: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23. Decision based on Non-MTUS Citation FOOD AND DRUG ADMINISTRATION (FDA) AND [HTTP://WWW.DRUGS.COM/PRO/FIORINAL.HTML](http://www.drugs.com/pro/fiorinal.html).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines BARBITURATE-CONTAINING ANALGESIC AGENTS (BCAs) Page(s): 23.

Decision rationale: Fioricet contains butalbital, acetaminophen, and caffeine. The Chronic Pain Guidelines indicate that barbiturate-containing analgesic agents are not recommended for chronic pain. There is no clinical evidence concerning the analgesic efficacy of barbiturate-containing analgesics. In this case, the patient has been taking Fioricet as far back as 2012; however, there is no documentation available concerning functional improvements derived from this medication. Fioricet is not recommended for chronic pain. There is no discussion concerning the need for variance from the guidelines. Therefore, the request is not medically necessary.

LIDOCAINE/PRILOCAINE 2.5%-2.5% TOPICAL CREAM APPLY TO KNEE BID-QID: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines LIDODERM (LIDOCAINE PATCH) Page(s): 56-57.

Decision rationale: The Chronic Pain Guidelines indicate that topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or serotonin-norepineprine reuptake inhibitor (SNRI) anti-depressants or an antiepileptic drug (AED) such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Prilocaine is a local anesthetic commonly used for dermal anesthesia. In this case, the patient has been prescribed with this medication since 2012. Medical records submitted and reviewed indicate that the patient has been complaining of low back pain radiating to both legs, as well as neck and upper back pain. The widespread area of complaints cannot be considered as a type of localized peripheral pain. Furthermore, the patient is likewise being prescribed with tiagebine, a GABA analog; and Tofranil, a tricyclic antidepressant, considered as first line medications. There is no documentation of failure of treatment with first line therapy. The guideline criteria have not been met. Therefore, the request is not medically necessary.

NUCYNTA 100MG 1-2 TABS EVERY 6 HRS PRN PAIN #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 81. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, NON-GOING MANAGEMENT Page(s): 78. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, TAPENTADOL (NUCYNTA).

Decision rationale: The Chronic Pain Guidelines indicate that four (4) domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids. The domains are: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potential aberrant (or non-adherent) drug-related 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. Furthermore, the Official Disability Guidelines indicate that tapentadol (Nucynta) is recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids such as, constipation, nausea, or vomiting. In this case, patient has been prescribed with Nucynta since 2012 due to reports of constipation. However, the latest progress note reporting its analgesic effects and adverse reactions is dated December 2012. The current clinical and functional status is not known. The Guidelines require clear and concise documentation for ongoing management. Therefore, the request is not medically necessary.

NUCYNTA ER 200MG 2 TABS Q 12 HRS PAIN CONTROL #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 81. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS FOR CHRONIC PAIN Page(s): 78.

Decision rationale: The Chronic Pain Guidelines indicate that four (4) 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 potential aberrant (or non-adherent) drug-related 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. Furthermore, the Official Disability Guidelines indicate that tapentadol (Nucynta) is recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids such as, constipation, nausea, or vomiting. The FDA approved tapentadol immediate-release tablets for relief of moderate to severe acute pain. In this case, patient has been prescribed with Nucynta ER since 2012 due to reports of constipation. However, the latest progress note reporting its analgesic effects and adverse reactions is dated December 2012. The current clinical and functional status is not known. The Guidelines require clear and concise documentation for ongoing management. Therefore, the request is not medically necessary.

SUBUTEX 8MG #60 1 SL QID: 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 BUPRENORPHINE Page(s): 26-27.

Decision rationale: The Chronic Pain Guidelines indicate that buprenorphine (Subutex) is recommended for the treatment of opiate addiction. It is also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction. In this case, the patient has been complaining of chronic neck, shoulder, and low back pain radiating to lower extremities. He has been prescribed with opioids since 2012. Medical records submitted and reviewed do not provide evidence that the patient manifested with signs of opiate addiction. There is no documented indication for this medication. The guideline criteria were not met. Furthermore, the current clinical and functional status is not known. Therefore, the request is not medically necessary.

TIAGEBINE 4MG #180 2 TABS TID: 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 ANTIEPILEPSY DRUGS (AEDs) Page(s): 16-17.

Decision rationale: The Chronic Pain Guidelines indicate that antiepileptic drugs are considered for use for neuropathic pain. A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. In this case, patient has been prescribed with tiagabine since January 2013. However, medical records submitted and reviewed do not provide evidence of functional gains and pain relief associated with its use. Furthermore, the current clinical and functional status of the patient is not known. Therefore, the request is not medically necessary.

TRAZODONE 150MG #270 3 TID: 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), MENTAL ILLNESS &; STRESS CHAPTER.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) MENTAL ILLNESS AND STRESS SECTION, TRAZODONE.

Decision rationale: The Official Disability Guidelines indicate that trazodone is recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression, or anxiety. There is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. In this case, patient is a diagnosed case of insomnia; and has been prescribed with trazodone since 2012. However, medical records submitted and reviewed do not provide discussion regarding his sleep hygiene. There have been no reports of functional improvement derived from its use. Furthermore, the current clinical and functional status of the patient is not known. Therefore, the request is not medically necessary.

VOLTAREN TOPICAL GEL 1% QID PAIN: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 112.

Decision rationale: The Chronic Pain Medical Treatment Guidelines indicate that Voltaren gel is indicated for relief of osteoarthritis pain in joints to lend themselves to topical treatment such as ankles, elbows, feet, hands, knees, and wrists. In this case, the patient has been using Voltaren gel since 2012. However, there was no documentation of functional gains such as improved ability to perform activities of daily living or decreased pain scores from the use of this medication. In addition, the request does not specify a quantity to be dispensed. Therefore, the request is not medically necessary.

RANITIDINE 300MG #90 1 QD: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [HTTP://WWW.DRUGS.COM/RANITIDINE.HTML](http://www.drugs.com/ranitidine.html).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FOOD AND DRUG ADMINISTRATION (FDA), (RANITIDINE).

Decision rationale: The FDA states that ranitidine is an H2 receptor antagonist indicated in the treatment of active gastric or duodenal ulcers, or for endoscopically-diagnosed erosive esophagitis. In this case, the records reviewed did not provide any evidence that the employee has been diagnosed with active gastric or duodenal ulcers or erosive esophagitis. There are no subjective complaints or objective findings pertaining to the gastrointestinal system that

necessitates this medication. Furthermore, the current clinical and functional status is not known. Therefore, the request is not medically necessary.