

Case Number:	CM13-0032882		
Date Assigned:	12/06/2013	Date of Injury:	02/01/2005
Decision Date:	01/21/2014	UR Denial Date:	09/12/2013
Priority:	Standard	Application Received:	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 Anesthesiology has a subspecialty in Pain 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 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. 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:

This patient is a 58-year-old female who reported an injury on 02/01/2005. The clinical notes indicate that the patient's injuries involved the bilateral knees, right shoulder and arm, as well as low back with associated symptoms regarding mental distress, the left lower arm, bilateral hands, right ankle, upper back, chest, ribs, abdomen, and groin. The clinical notes indicate that the patient was initially injured as the result of a trip while walking on uneven ground, causing the patient to fall. Clinical notes also indicate that the patient was able to get up under her own strength and that the patient was provided ice packs and was seen for further treatment the following day. This patient is currently clinically assessed with lumbar radiculopathy, right knee internal derangement, right knee pain, right rotator cuff tear, right torso and flank musculoskeletal pain, a chronic pain syndrome, chronic pain related insomnia, myofascial syndrome, as well as prescription narcotic dependence, and chronic pain related depressive anxiety. The clinical notes indicate in the patient's treatment history that she has undergone right knee replacement which has resulted in failure and chronic pain with inability of an electrical stimulator to successfully provide pain relief. The patient's current pain medication regimen includes Flector patch 1.3%, Norco 10/325 mg, Pamelor 50 mg, lactulose 10 gram/15 mL, Lidoderm patch 5%, Butrans 10 mcg, and Fluriflex ointment.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector patch 1.3% #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics Page(s): 111-113.

Decision rationale: The MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally 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. However, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The MTUS guidelines indicate that Voltaren® Gel 1% (diclofenac) is an FDA-approved agent indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most recent clinical evaluation of the patient presented for review is dated 11/26/2013. Within regard to the requested Flector patch, the documentation submitted for review indicates that with the patient's current medications, he is maintained on average a 2/10 to 3/10 and without medications the patient's pain score is 10/10. The clinical notes also indicate that within pain medications as prescribed, the patient's pain score is 5/10 VAS. Furthermore, the clinical notes indicate that the patient was initially prescribed Flector patches on 05/02/2013 given that the patient was unable to utilize oral diclofenac. However, while clinical notes indicate the patient has a history of acid reflux and GI upset with the use of nonsteroidal anti-inflammatory drugs, the guidelines indicate that topical nonsteroidal anti-inflammatory drugs have been shown in med analysis to be superior to placebo in the first 2 weeks of treatment for osteoarthritis but either not afterwards or with diminishing affect over a 2 week period. There is no clear indication in the most recent clinical notes submitted for review that the patient has any demonstrated efficacy from the use of Flector patches. Therefore, the request for Flector patch is not certified.

Norco 10/325 mg #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): 91.

Decision rationale: The MTUS indicates that Hydrocodone/Acetaminophen is indicated for moderate to moderately severe pain. The MTUS also indicates a recommendation for the 4 A's for Ongoing Monitoring. These four domains for monitoring have been summarized as the "4

A's" and include monitoring for include analgesia, activities of daily living, adverse side effects, and 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 clinical notes from 11/07/2013 address the patient's Norco indicating that the patient's Norco provides approximately 50% to 70% pain relief and improved function with the patient able to get out of the house, care for herself independently, and do light housework. Without the medication, the patient indicates just wanting to lie around in bed due to pain. However, clinical notes indicate that the patient is currently recommended for weaning of Norco. Nonetheless, there is no clear clinical rationale provided for the necessity of a refill of Norco currently with a dose count of 240 given that the patient is currently recommended for weaning. Furthermore, the notes submitted for review provide that the patient has been prescribed Butrans for weaning of narcotics. Therefore, the request for Norco is not certified.

Pamelor 50 mg: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Anti-depressants Page(s): 13.

Decision rationale: The MTUS guidelines indicate that tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Also, the optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. While guidelines indicate that the optimal duration of treatment is not known with this medication, there is a lack of documentation submitted for review indicating the patient's pain is currently in remission with the use of Pamelor. However, given that the patient is currently diagnosed with depression secondary to chronic pain after having undergone evaluation, continued treatment with Pamelor would be supported for alleviating symptoms of the patient's depression. Therefore, the request for Pamelor is certified.

Lactulose: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Initiating Therapy,. Decision based on Non-MTUS Citation Lactulose: MedlinePlus Drug Information: Retrieved from: www.nlm.nih.gov/medlineplus/druginfo/meds/a682338.html.

Decision rationale: The MTUS/ACOEM guidelines do not specifically address lactulose. Clinical literature states that Lactulose is a synthetic, non-digestible sugar used in the treatment of chronic constipation. Lactulose is also used to reduce the amount of ammonia in the blood of patients with liver disease. The MTUS states that a consideration in initiating opioid therapy is the initiation also of prophylactic treatment of constipation. While the guidelines detail the recommendation for prophylactic treatment of constipation for patients on opioid therapy, there is a lack of documentation submitted for review indicating that the patient has complaints of constipation. . However, based on the recommendation of the guidelines, prophylactic treatment with lactulose 10 grams/15 mL is medically necessary and appropriate.

Lidoderm patch 5% #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics Page(s): 111-113.

Decision rationale: The MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally 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; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The MTUS guidelines also indicate that Lidocaine in a transdermal application is recommended for neuropathic pain and recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy such as a tri-cyclic or serotonin-norepinephrine reuptake inhibitors antidepressants or an anti-epileptic drug such as gabapentin or Lyrica. 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. 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. Nonetheless, while Lidoderm patches may be considered for use for treatment of neuropathic pain, there is a lack of documentation submitted for review indicating that the patient has findings on examination consistent with a neuropathology. The patient's primary complaints and examination findings are limited to musculoskeletal complaints. Given the above, the request for Lidoderm is non-certified.

Butrans 10 mcg #4: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Buprenorphine Page(s): 66.

Decision rationale: The MTUS guidelines indicate that Buprenorphine is recommended for treatment of opiate addiction. It is Also, it is recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction. 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). Notes indicated the patient has had prior use of Butrans. However, there is no indication currently that the patient is utilizing this medication and the patient is noted to currently be on narcotic analgesics. The documentation submitted for review states that the patient is currently clinically assessed with narcotic dependence and notes indicate that the patient has not yet received a refill of Butrans patches. While guidelines support the recommendation for use of Butrans and an option for chronic pain, especially after detoxification of patients who have a history of opioid addiction, there is a lack of documentation to indicate that the patient has yet undergone a detox program.

Fluriflex ointment: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics Page(s): 111-113.

Decision rationale: MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally 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; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. CA MTUS states non-steroidal antiinflammatory agents have limited demonstrated efficacy in clinical trials and have been inconsistent with most studies being small and of short duration. They have been found in studies to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical Nonsteroidal anti-inflammatory drugs (NSAIDs) have been shown to be superior to placebo for 4 to 12 weeks. However, again the effect appeared to diminish over time and it was stated that further research was required to

determine if results were similar for all preparations. Note indicate that the patient has been prescribed Fluriflex ointment since at least 08/30/2013. Clinical notes on 08/30/2013 indicate that the patient was having some decrease in pain and increased mobility which the patient attributed to the use of Fluriflex ointment. Nonetheless, as guidelines indicate that nonsteroidal anti-inflammatory agents are indicated as primarily beneficial only in short duration and as there is a lack of documentation indicating further improvement with the use of Fluriflex ointment.