

Case Number:	CM14-0206945		
Date Assigned:	12/18/2014	Date of Injury:	09/19/2004
Decision Date:	02/11/2015	UR Denial Date:	12/02/2014
Priority:	Standard	Application Received:	12/10/2014

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 Family Practice and is licensed to practice in North Carolina. 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 a 51-year-old with a reported date of injury of 09/19/1994. The patient has the diagnoses of myalgia, shoulder joint pain, brachial neuritis, post laminectomy syndrome of the cervical and lumbar spine, spinal enthesopathy, muscle spasm and opioid dependence. Previous treatment modalities have included acupuncture, surgery, TENS and cervical epidural steroid injections. Per the most recent progress notes provided for review from the primary treating physician dated 11/19/2014, the patient had complaints of continued constant sharp pain that is rated a 3/10. The physical exam noted tenderness in the lumbar paraspinal muscles and decreased lumbar range of motion. Treatment plan recommendations included home stretching and continuation of medication and pending authorization for home health nurse.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 60mg, #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta Page(s): 24.

Decision rationale: The California chronic pain medical treatment guidelines section on duloxetine states: Recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (Cymbalta) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the precautions/Hepatotoxicity section of the prescribing information for Cymbalta. The patient has the diagnosis of neuropathic pain in the form of brachial neuritis. The patient does not have any recorded liver problems. Therefore criteria for the use of this medication have been met and the request is medically necessary.

Lyrica 150mg, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica Page(s): 19.

Decision rationale: The California chronic pain medical treatment guidelines section on Lyrica states: Pregabalin (Lyrica, no generic available) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) Dose adjustment is necessary in patients with renal insufficiency. The antiepileptic agents gabapentin and pregabalin have attained widespread usage in the treatment of painful diabetic peripheral neuropathy (DPN). This patient does not have the diagnoses of diabetic neuropathy, fibromyalgia or post-herpetic neuralgia. Therefore the patient does not have an indicated use for this medication per the FDA and the California MTUS, Therefore the request is not medically necessary.

Morphine Sulfate 15mg, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Recommendations of Opioid Use. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states: On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: 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 "4 A's" (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. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) 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 does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids (a) If the patient has returned to work (b) If the patient has improved functioning and pain (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) The long-term use of this medication is not recommended unless certain objective outcome measures have been met as defined above. There is no provided objective outcome measure that shows significant improvement in function besides the subjective statement that the opioids improve the

patient's function. The most recent progress notes do not mention work status. The progress notes state that patient has improvement in pain but no objective measures such as VAS scores are given. Earlier progress notes do mention improvement in VAS scores but not the most recent ones. In addition, the patient's cumulative MED is far greater than 120 MED recommended per the California MTUS. For these reasons all criteria for ongoing and continued use of the medication have not been met. Therefore the request is not medically necessary.

Diazepam 5mg, #150: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The California chronic pain medical treatment guidelines section on benzodiazepines stated: Benzodiazepines Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) This medication is not recommended per the California MTUS for chronic ongoing use. They are the treatment of choice in very few instances. There is no indication of failure of other first line anxiety medications. Therefore the request is not medically necessary.

Meloxicam 7.5mg, #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 71-73.

Decision rationale: The California chronic pain medical treatment guideline section on NSAID therapy states: 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 naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) This medication is recommended at the lowest possible dose for the shortest period of time. The duration of "shortest period of time" is not defined in the California MTUS. The patient has no mentioned cardiovascular, renovascular or gastrointestinal side-effects or risk factors. The dosage prescribed is within recommendations. Therefore the request is medically necessary.

Methadone 10mg, #150: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Recommendations of Opioid Use. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Methadone Page(s): 61-62.

Decision rationale: The California chronic pain medical treatment guidelines section on methadone states: Methadone Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008) Steps for prescribing methadone: (1) Basic rules- Weigh the risks and benefits before prescribing methadone.- Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction.- Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments. (2) Know the information that is vital to give the patient:- Don't be tempted to take more methadone than prescribed if you are not getting pain relief. This can lead to a dangerous build-up that can cause death.- All changes in methadone dose should be made by your treating practitioner.- Methadone can make your breath slow down, or actually stop.- Methadone can slow down your heartbeat and you might not be able to detect this.- If you feel like you are having an irregular heartbeat, dizziness, light-headedness or fainting, call your doctor or clinic immediately. (FDA, 2006) (3) Be familiar with the current SAMHSA health advisory on methadone - The medication has become more accessible to unauthorized users.- It can accumulate in potentially harmful doses (especially during the first few days of treatment.- There has been a rise in Methadone-associated mortality. (SAMHSA, 2004) (4) Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, "Can Methadone be used for pain control?" No separate registration is required to prescribe methadone for treatment of pain. (DEA, 2006) (5) Read the new prescribing information for Methadone and the new patient information section. (Roxane, 2006) (6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications. This medication is indicated as a second-line agent in the treatment of chronic pain. In the progress notes the patient reports pain level as 10/10 without medications and a 4-5/10

with medications. The patient does have the diagnoses of chronic opioid dependence. This however is a second line treatment option for chronic pain and the patient has not exhausted first line treatment option either per the California MTUS or the ODG. Therefore the request has not met criteria as per the California MTUS guidelines and is not medically necessary.