

Case Number:	CM15-0020393		
Date Assigned:	02/10/2015	Date of Injury:	06/29/2000
Decision Date:	03/30/2015	UR Denial Date:	01/27/2015
Priority:	Standard	Application Received:	02/03/2015

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: Pennsylvania
 Certification(s)/Specialty: Internal Medicine

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 53 year old female with a date of injury of 6/29/2000. Diagnoses include chronic spine pain status post lumbar discectomy and subsequent lumbar spinal fusion with post laminectomy syndrome, and dental issues. Past medical history includes diabetes and obesity. Treatment has included surgery, epidural steroid injections, medication, and intrathecal pain pump with revisions. Progress notes from February 2014 to January 2015 were submitted, as well as one progress note from January 2001. The progress note of January 2001 notes medications including soma, norco, and desyrel (trazodone). Examination on 1/15/15 showed mildly antalgic gait with the torso in slight forward flexion. Medications included methadone, norco, oxycodone, additional oral medications, and intrathecal fentanyl/clonidine/bupivacaine. It was noted that a most recent urine drug test was acceptable and that drug testing was done periodically on an unannounced basis. Medications in September 2014 were listed as amitiza, Cymbalta, ibuprofen, lyrica, methadone, norco, pilocarpine, soma, trazodone, as well as intrathecal medications. Discussion of medications in August 2014 noted norco for dental pain, soma as a muscle relaxer, Cymbalta for pain and mood symptoms, ibuprofen to reduce inflammation, lyrica for myofascial pain, trazodone to aid with sleep, and amitiza for constipation from chronic opioid use along with dietary measures; additional medications listed at that visit include methadone, pilocarpine, pump medications, and medications for diabetes. It was documented that the injured worker had a signed opioid prescribing agreement. Work status and activities of daily living were not discussed. A dental consultant documented presence of xerostomia. On 1/27/15, Utilization Review modified or non-certified requests for Cymbalta 60

mg #60 with 4 refills, soma 350 mg #30 with 2 refills, lyrica 75 mg #150 with 3 refills, ibuprofen 600 mg #90 with 3 refills, pilocarpine 5 mg #120 with 6 refills, norco 10/325 #60, trazodone 100 mg #30 with 2 refills, and amitiza 24mcg #60, citing the MTUS and ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 60 mg #60 with 4 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines antidepressants p. 14-16.

Decision rationale: Cymbalta is a serotonin and norepinephrine reuptake inhibitor which is FDA approved for anxiety, depression, diabetic neuropathy, and fibromyalgia, and which is sometimes used off-label for neuropathic pain and radiculopathy. The MTUS states that antidepressants are recommended as a first line option for neuropathic pain and as a possibility for non-neuropathic pain. 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. The documentation from the physician notes that cymbalta was prescribed for pain and mood symptoms. Per the records submitted, it has been prescribed for at least 6 months. The documentation submitted did not address activities of daily living, work status, or sleep quality; psychological assessment was not documented. There was mentioned in September 2014 that the injured worker had weaned methadone down to 40 mg daily, and this dose was continued in January 2014. No other discussion of decrease in medications was documented, and prescriptions for multiple pain medications including oral and intrathecal pain medications continued. Improvement in pain was not documented. Due to lack of demonstration of functional improvement and lack of documentation of psychological assessment, the request for cymbalta is not medically necessary.

Soma 350 mg #30 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (soma) p. 29, muscle relaxants p. 63-66 Page(s): 29, 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per

the MTUS Chronic Pain Medical Treatment Guidelines, Soma (carisoprodol), a sedating centrally acting skeletal muscle relaxant, is not recommended and not indicated for long term use. This injured worker has chronic pain with no evidence of prescribing for flare-ups. Prescribing has occurred for at least 6 months and possibly for years, and the quantity prescribed implies long term use, not a short period of use for acute pain. No reports show any specific and significant improvements in pain or function as a result of Soma. Per the MTUS, Soma is not recommended for chronic pain and has habituating and abuse potential. For these reasons, the request for soma is not medically necessary.

Lyrica 75 mg #150 with 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants Page(s): p. 16-22.

Decision rationale: Per the MTUS, antiepilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Lyrica (pregabalin) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, and is FDA approved for these indications as well as for fibromyalgia. Side effects include edema, central nervous system depression, weight gain, blurred vision, somnolence, and dizziness. It has been suggested that this medication be avoided in patients who have problems with weight gain. The injured worker was noted to have a diagnosis of obesity. Lyrica has been prescribed for at least 6 months without documentation of functional improvement. Work status and activities of daily living were not addressed. The injured worker continues to be prescribed multiple medications for pain. Due to lack of functional improvement, the request for Lyrica is not medically necessary.

Norco 10/325 mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96.

Decision rationale: There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals and return to work. There should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies", and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. Work status and activities of daily living were not addressed. The injured worker continues to be prescribed multiple medications for pain. Norco has been prescribed for at least 6 months and possibly for years. There was mentioned in September 2014 that the injured worker had weaned methadone down to 40 mg daily, and this dose was

continued in January 2014. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS with the exception of urine drug testing and the presence of an opioid contract, which was documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. The physician documented that a most recent urine drug test was acceptable and that drug testing was done periodically on an unannounced basis. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. As currently prescribed, and due to the lack of functional improvement in spite of chronic use, norco does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

Trazodone 100 mg #30 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines antidepressants p. 14-16. Decision based on Non-MTUS Citation chronic pain chapter: insomnia treatment

Decision rationale: Trazodone is a tetracyclic antidepressant used to treat depression and anxiety disorders. Per the MTUS, antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain, unless they are poorly tolerated, contraindicated, or ineffective. 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. There was no documentation of functional improvement as a result of prescription of trazodone, which has been prescribed for at least 6 months and possibly for years. It was noted that trazodone was prescribed to aid with sleep. Sedating antidepressants such as amitriptyline, trazodone, and mirtazapine have been used to treat insomnia; there is less evidence to support their use for insomnia but they may be an option in patients with coexisting depression. Trazodone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia were not addressed. The treating physician has not addressed major issues affecting sleep in this patient, including the use

of other psychoactive agents like opioids, which significantly impair sleep architecture, and depression. Due to lack of adequate evaluation of sleep disturbance and lack of functional improvement, the request for trazodone is not medically necessary.

Ibuprofen 600 mg #90 with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): p. 67-73.

Decision rationale: Per the MTUS, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDS are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain, NSAIDs should be used for the short term only. The documentation indicates prescribing for chronic pain rather than for an acute exacerbation of low back pain. Ibuprofen has been prescribed for at least 6 months. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. Although blood pressure was periodically recorded, there was no documentation of monitoring of blood tests. Work status and activities of daily living were not addressed. The injured worker continues to be prescribed multiple medications for pain. Due to length of use not in accordance with the guidelines, lack of demonstration of functional improvement, and potential for toxicity, the request for ibuprofen is not medically necessary.

Pilocarpine 5 mg #120 with 6 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: Pilocarpine. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015. pdr.net: pilocarpine

Decision rationale: The MTUS and ODG are silent with regards to pilocarpine. Pilocarpine is a cholinergic agonist indicated for treatment of dry mouth in Sjogren's syndrome or from salivary gland hypofunction caused by radiotherapy for head and neck cancer. Specific indication for this medication was not discussed in the records submitted. The injured worker did not have

diagnoses of Sjogren's syndrome or head and neck cancer. A dental consultant documented presence of xerostomia, but did not discuss treatment for this. No progress notes addressed the use of pilocarpine, which has been prescribed for months. Due to lack of an approved indication, the request for pilocarpine is not medically necessary.

Amitiza 24 mcg #60: Overturned

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, Opioid-induced constipation treatment

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids, initiating therapy Page(s): p. 77. Decision based on Non-MTUS Citation chronic pain chapter: opioid induced constipation pdr.net: amitiza

Decision rationale: The MTUS notes that when initiating therapy with opioids, prophylactic treatment of constipation should be initiated. Per the ODG, constipation occurs commonly in patients receiving opioids. If prescribing opioids has been determined to be appropriate, prophylactic treatment of constipation should be initiated. First line treatment includes increasing physical activity, maintaining appropriate hydration, and diet rich in fiber. Some laxatives may help to stimulate gastric motility, and other medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Per the prescribing information, Amitiza (lubiprostone) is approved for treatment of opioid-induced constipation in adults with chronic, non-cancer pain. The treating physician documented that amitiza was prescribed for constipation from chronic opioid use along with dietary measures. The injured worker has been prescribed multiple medications including several opioids, and use of dietary measures was discussed. For these reasons, the request for amitiza is medically necessary.