

Case Number:	CM13-0062759		
Date Assigned:	06/09/2014	Date of Injury:	10/04/1996
Decision Date:	08/05/2014	UR Denial Date:	11/12/2013
Priority:	Standard	Application Received:	12/09/2013

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 Anesthesiology and Pain Medicine and is licensed to practice in Florida. 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 injured worker is a 52-year-old female who reported an injury on October 04, 1996 with the mechanism of injury not cited within the documentation provided. In the clinical notes dated November 01, 2013, the injured worker was being seen for an intrathecal pump refill under ultrasound guidance. It was noted that the injured worker also complained of mid back, low back, buttock and leg pain. Previous treatments included physical therapy, lower back surgeries, and prescribed pain medications. The physical examination revealed the injured worker to be in moderate to severe distress with prolonged sitting greater than 5 minutes. The evaluation of the injured worker's evaluation of the thoracolumbar spine showed multiple well-healed surgical scars. There was a decreased range of motion secondary to surgical changes as well as pain. There was moderate to severe pain past 30 degrees of flexion, 10 degrees of extension, and a positive straight leg raise bilaterally. Deep tendon reflexes were present but diminished bilaterally and there was diffuse decreased disc sensation to pinprick, with the left greater than the right, of which did not follow dermatomal distribution. The lumbosacral spine had severe myofasciitis from the mid lumbar area down to the sacrum. There was moderate to severe sacroiliitis noted bilaterally, and significant sustained myofascial spasm in the quadratus lumborum, sacroiliac musculature into the right buttock and piriformis. The pump was refilled with 20cc of preservative-free morphine sulfate 35mg/cc, baclofen 0.3mg/cc and clonidine 0.3mg/cc, fentanyl 0.3mg/cc. The treatment plan included for the injured worker to continue with intrathecal medications as well as oral medications. The diagnoses included post laminectomy syndrome lumbar, arachnoiditis with lower extremity radiculitis, myofasciitis, chronic opiate therapy for pain, situational depression and indwelling intrathecal and fusion system. The injured worker's pain medication regimen included methadone 10mg twenty per day (200mg per day), oxycodone 30mg tablets (9 per day), Lunesta 2mg (2 per day), Fioricet tabs (once a day), Soma

350mg (8 per day), Neurontin 800mg (1 a day), Skelaxin 800mg (3 times a day), Lexapro 20mg (every day), Elavil 50mg (3 per day), ibuprofen 800mg (twice a day), baclofen 10mg (6 per day), Tagamet 400mg (twice a day), promethazine 25mg (2 per day), and AlliMAX cream 5.5% (as needed).

IMR ISSUES, DECISIONS AND RATIONALES

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

Methadone 10mg (20 per day): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Methadone, Opioids Page(s): 61-62, 78, 86.

Decision rationale: The request for methadone is not medically necessary. The California MTUS Guidelines state that methadone is recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. Methadone should be only be prescribed by providers experienced in using it. Steps for prescribing methadone include weighing the risks and benefits before prescribing methadone; and avoid prescribing 40mg methadone tablets for chronic nonmalignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction. 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 injured worker should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications. The guidelines also state that ongoing monitoring should occur and should include monitoring of pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent drug-related) behaviors. The guidelines also recommend that opioid dosing not exceed 120mg oral morphine equivalence per day (MED), and for injured workers taking more than 1 opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. In the clinical notes provided for review, it is annotated that the injured worker has been in use of an indwelling intrathecal and fusion system since at least May 2013 and has the pump refilled on a monthly basis. There is also annotation that the injured worker has been on methadone since May 2013 and several other oral pain medications. However, there is a lack of documentation of the injured worker's pain level status with the use of these pain medications. There is also a lack of documentation of the injured worker's functional status with the use of these pain medications. Furthermore, the request greatly exceeds the recommended MED equivalent by an excess of 2280mg per day and in adjunct with other opioids, the dosage exceeds the recommendation by 2684mg. Therefore, the request is not medically necessary.

Roxicodone (30mg - 9 per day): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78,80, 86, 92.

Decision rationale: The request for Roxicodone is not medically necessary. The California MTUS Guidelines state that opioids for chronic appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (greater than 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. The guidelines also recommend ongoing monitoring to include pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. The guidelines also recommend that dosing not exceed 120mg or morphine equivalents per day, and for injured workers taking more than 1 opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. Rarely, and only after pain management consultation, should the total daily dose of opioids be increased above 120mg or morphine equivalence. Roxicodone is indicated for moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. In the clinical notes provided for review, it is annotated that the injured worker has an indwelling intrathecal infusion system that uses morphine sulfate, baclofen, clonidine, and fentanyl. However, there is a lack of documentation of the injured worker's pain level status with the use of oral medications and with the indwelling intrathecal pain pump. The injured worker has had the oral medication and the intrathecal pain pump since May 2013. Additionally, the injured worker is taking 30mg of Roxicodone 9 times per day, which greatly exceeds the recommended daily morphine equivalent dose by 285mg. The injured worker takes Roxicodone in conjunction with methadone and, in combination; the dosage greatly exceeds the morphine equivalent dose by 2685mg. Therefore, the request is not medically necessary.

Lunesta (2mg - 2 per day): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter, Insomnia Treatment.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Insomnia treatment.

Decision rationale: The request for Lunesta is not medically necessary. The Official Disability Guidelines (ODG) state that insomnia treatment such as Lunesta is not recommended for long-term use, but recommended for short-term use. Lunesta is a benzodiazepine-receptor agonist, which works by selectively binding two type 1 benzodiazepine receptors in the central nervous system. The benzodiazepine-receptor agonists are scheduled for controlled substances, which mean they have the potential for abuse and dependency. Although direct comparisons between benzodiazepines and nonbenzodiazepine hypnotics have not been studied, it appears that the nonbenzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action. In the clinical notes provided for review, there was a lack of

documentation of the injured worker complaining of insomnia. There is also a lack of documentation of the injured worker's duration of sleep with or without disturbances. In addition, the injured worker has been on the prescription of Lunesta since May 2013 without the documentation of efficacy. Therefore, the request is not medically necessary.

Fioricet (4 times per day): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate Containing Analgesics (BCAs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents (BCAs) Page(s): 23.

Decision rationale: The request for Fioricet is not medically necessary. The California MTUS Guidelines state that barbiturate-containing analgesic agents (BCAs) is not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. There is a risk of medication overuse as well as rebound headache. In the clinical notes provided for review, there is a lack of documentation of the injured worker's pain level status, as well as a lack of documentation of the efficacy of the pain medications taken. There is also a lack of documentation of the dose of Fioricet is to be taken. Furthermore, the guidelines do not recommend the usage of BCAs for chronic pain. Therefore, the request is not medically necessary.

Skelaxin (800mg -3 times per day): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Metaxalone (Skelaxin) Page(s): 63, 61.

Decision rationale: The request for Skelaxin is not medically necessary. The California MTUS Guidelines state that Skelaxin is recommended with caution as a second-line option for short-term pain relief in injured workers with chronic low back pain. Skelaxin is a muscle relaxant that is reported to be relatively nonsedating. In the clinical notes provided for review, there is a lack of documentation of the injured worker's pain level status with or without the use of the prescribed pain medications. It is also annotated that the injured worker has been on Skelaxin since May 2013. In addition, the injured worker is on another muscle relaxant, Soma. Therefore, the request is not medically necessary.

Soma (350mg - 8 per day): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) Page(s): 29.

Decision rationale: The request for Soma is not medically necessary. The California MTUS Guidelines state Soma is not recommended. The guidelines state that Soma is not indicated for long-term use. It is a commonly prescribed centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule for controlled substances). Soma is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers, the main concern is accumulation of meprobamate. Soma abuse has also been noted in order to augment or offset effects of other drugs. This includes the following: 1) increasing sedation of benzodiazepines or alcohol; 2) used to prevent side effects of cocaine; 3) used with tramadol to produce relaxation and euphoria; 4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin; and 5) as a combination with codeine. In the clinical notes provided for review, there was a lack of documentation of the injured worker's pain level status with or without the use of the prescribed pain medications. It is also documented that the injured worker has been on Soma since May 2013 along with the use of another muscle relaxant. Furthermore, the guidelines do not recommend the use of Soma for long-term use. Therefore, the request is not medically necessary.

Ibuprofen (800mg - 3 times per day): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-68.

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

Decision rationale: The request for ibuprofen is not medically necessary. The California MTUS Guidelines state that NSAIDs for chronic low back pain is recommended as an option for short-term symptomatic relief. NSAIDs were no more effective than other drugs, such as acetaminophen, narcotic analgesics, and muscle relaxants. Guidelines state that NSAIDs had more adverse effects than placebo and acetaminophen, but fewer effects than muscle relaxants and narcotic analgesics. In the clinical notes provided for review, there was a lack of documentation of the injured worker's pain level status along with the efficacy of the prescribed pain medications. The injured worker has been on ibuprofen since June 2013. There is also a lack of documentation of the rationale for the use of ibuprofen. Furthermore, the guidelines recommend the use of NSAIDs for short-term symptomatic relief. Therefore, the request is not medically necessary.

Baclofen (10mg - 6 per day): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity/Antispasmodic Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-64.

Decision rationale: The request for baclofen is not medically necessary. The California MTUS Guidelines state that baclofen is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain. In the clinical notes provided for review, there is a lack of documentation of the injured worker's pain level status along with the efficacies of the prescribed pain medications. It is also annotated that the injured worker is on two other muscle relaxants. There is also a lack of documentation of the frequency of the prescribed medication of baclofen. Furthermore, the guidelines recommend the use of muscle relaxants for a short duration of time, of which the injured worker has been on baclofen since June 2013. Therefore, the request is not medically necessary.

Tagamet (400mg - 2 times per day): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: The request for Tagamet is not medically necessary. The California MTUS Guidelines state that to determine if the injured worker has at risk for gastrointestinal events, the following criteria should be evaluated, age greater than 65 years, history of peptic ulcer, GI bleeding or perforations, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high-dose/multiple NSAIDs (i.e. NSAID and low-dose ASA). In the clinical notes provided for review, there is a lack of documentation of the injured worker having previous GI issues such as peptic ulcer or GI bleeding. There is also a lack of documentation of the prescribed pain medications' side effects of which the injured worker is on. Therefore, the request is not medically necessary.

Promethazine (25mg - 2 per day): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter, Antemetics (for opioid nausea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Antiemetics (for opioid nausea).

Decision rationale: The request for promethazine is not medically necessary. The Official Disability Guidelines (ODG) state that anti-emetics (for opioid nausea) are not recommended for nausea and vomiting secondary to chronic opioid use. Promethazine is recommended as a sedative and anti-emetic in preoperative and postoperative situations. In the clinical notes

provided for review, there was a lack of documentation of the injured worker having signs and symptoms of nausea and vomiting secondary to chronic opioid use. There is also a lack of documentation of the injured worker's side effects with the use of the prescribed medications. Furthermore, the guidelines do not recommend the use of anti-emetics for chronic opioid use. Therefore, the request is not medically necessary.

LMX Cream (5.5%): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: The request for LMX cream is not medically necessary. The California MTUS Guidelines state topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded program that contains at least one drug (or drug class) that is not recommended, is not recommended. In the clinical notes provided for review, there is a lack of documentation of the injured worker's pain level status along with the efficacy of the prescribed pain medications. There is also a lack of documentation of the area of use for the LMX cream and the frequency. Furthermore, it is unclear what the use of LMX cream 5.5% is indicated for. Therefore, the request is not medically necessary.