

Case Number:	CM14-0054904		
Date Assigned:	08/08/2014	Date of Injury:	10/17/2011
Decision Date:	09/22/2014	UR Denial Date:	04/17/2014
Priority:	Standard	Application Received:	04/24/2014

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 Anesthesiology, has a subspecialty in 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 53-year-old male with a reported date of injury on 10/17/2011. The injury reportedly occurred when the injured worker was stuck in a tree, dangling by his right foot for several minutes. His diagnoses were noted to include herniated disc to the lumbar region, enthesopathy of the ankle and tarsus, degenerative joint disease of the knee/lower leg, and lumbar spine radiculopathy. His previous treatments were noted to include medication. The progress note dated 07/30/2014 revealed the injured worker complained of burning pain rated 5/10. The physical examination of the lumbar spine revealed an antalgic gait and tenderness noted to the right sacroiliac joint and absent in the bilateral buttocks. The extension of the lumbar spine was negative for back pain, and the range of motion of the lumbar spine was restricted. The Faber's test was positive, as well as the pelvic compression test, but the stork test was not performed due to knee pain. The motor strength was diminished in the extensor hallucis longus and right dorsiflexors. The physical examination of the right knee revealed joint line tenderness with patellofemoral facet tenderness. There was a positive varus/valgus laxity and McMurray's test. The right fibular-talar ligament was painful to palpation. The range of motion to the knee was noted to be diminished and there was crepitus noticed on movement of the knee. The injured worker indicated he had stopped all of his medications except for tramadol. The injured worker complained of itching as well as bumps on his scalp. The injured worker reported he had stopped the Theramine and Naprosyn. The provider indicated the injured worker had unacceptable gastrointestinal side effects with oral agents, and topical agents were more appropriate in managing symptoms. The Request for Authorization Form was not submitted within the medical records. The request was for tizanidine 4 mg #60, Theracodophen 90 convenience pack Theramine #90, hydrocodone 10/325 mg #60, Theraproxen #90, naproxen 250

mg #60, and Terocin patches #1; however, the provider's rationale was not submitted within the medical records.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tizaidine 4mg #60: 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 Page(s): 63.

Decision rationale: The request for Tizaidine 4mg #60 is not medically necessary. The injured worker has been utilizing this medication since at least 04/2014. The California Chronic Pain Medical Treatment Guidelines recommend non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. There is a lack of documentation regarding efficacy of this medication. There is a lack of clinical findings consistent with muscle spasms. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.

Hydrocodone 10/325mg #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, On-going Management Page(s): 78.

Decision rationale: The request for Hydrocodone 10/325mg #60 is not medically necessary. The injured worker complained of severe side effects with oral analgesics. According to the California Chronic Pain Medical Treatment Guidelines, the ongoing use of opioid medications may be supported with detailed documentation of pain relief, functional status, appropriate medication use, and side effects. The guidelines also state that the 4 A's for ongoing monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors, should be addressed. There is a lack of decreased pain on a numerical scale with the use of medications. There is a lack of improved functional status with the use of medications. The injured worker has severe side effects with the use of oral medications. There is a lack of documentation regarding whether the injured worker has had consistent urine drug screens and when the last test was performed. Therefore, due to the lack of documentation of evidence of

significant pain relief, improved functional status, and without details regarding urine drug testing to verify appropriate medication use and the absence of aberrant behavior, the ongoing use of opioid medications is not supported by the guidelines. Additionally the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

Theraproxen 90: 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): 67. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Theramine.

Decision rationale: The request for Theraproxen 90 is not medically necessary. Theraproxen contains Theramine and naproxen. Theramine consists of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, gamma aminobutyric acid, and L-serine. According to the Official Disability Guidelines, Theramine is not recommended. Theramine is a medical food that is a proprietary blend of gamma aminobutyric acid and choline bitartrate, L-arginine, and L-serine. It is intended for the management of pain syndromes to include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The guidelines state gamma aminobutyric acid has no high quality peer reviewed literature that suggests that GABA is indicated. The guidelines state choline has no known medical need. The guidelines state L-arginine is not indicated in current references for pain and inflammation. The guidelines state L-serine has no indication for use. In the manufacturer study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. However, until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The California Chronic Pain Medical Treatment Guidelines recommend NSAIDs 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. The guidelines recommend NSAIDs as a second line treatment after acetaminophen for acute exacerbations of chronic pain. In general, there was conflicting evidence that NSAIDs are more effective than acetaminophen for acute low back pain. The guidelines recommend NSAIDs as an option for short term symptomatic relief of chronic low back pain. A review of the literature on drug relief for low back pain suggested NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, or muscle relaxants. There is a lack of documentation regarding efficacy of this medication. The injured worker indicated he had severe gastrointestinal upset with previous Naprosyn, and the guidelines do not recommend Theramine for use. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

Naproxen 250mg #60: 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): 67-68.

Decision rationale: The request for Naproxen 250mg #60 is not medically necessary. The injured worker complained of severe gastrointestinal upset with previous utilization of naproxen. The California Chronic Pain Medical Treatment Guidelines recommend NSAIDs 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. The guidelines recommend NSAIDs as a second line treatment after acetaminophen for acute exacerbations of chronic pain. In general, there was conflicting evidence that NSAIDs are more effective than acetaminophen for acute low back pain. The guidelines recommend NSAIDs as an option for short term symptomatic relief of chronic low back pain. A review of the literature on drug relief for low back pain suggested NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, or muscle relaxants. The injured worker indicated he had severe gastrointestinal upset with the previous utilization of Naprosyn. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.

Terocin patches #1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105, 111, 112.

Decision rationale: The request for Terocin patches #1 is not medically necessary. The injured worker has been utilizing this medication since at least 04/2014. The California Chronic Pain Medical Treatment Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines state topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines state capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain and after there has been evidence of a trial of first line therapy (tricyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Terocin is a topical analgesic containing capsaicin/lidocaine/menthol/methyl salicylate, and capsaicin and the cream or gel form of lidocaine are not recommended by the guidelines. Additionally, the request

failed to provide the frequency at which this medication has been utilized. Therefore, the request is not medically necessary.