MAXIMUS Federal Services

Case Number:	CM15-0170737		
Date Assigned:	09/11/2015	Date of Injury:	02/11/1997
Decision Date:	10/26/2015	UR Denial Date:	08/25/2015
Priority:	Standard	Application Received:	08/31/2015

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: Tennessee, Florida, Ohio
Certification(s)/Specialty: Surgery, Surgical Critical Care

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 54 year old female sustained an industrial injury to the low back on 2-11-97. Magnetic resonance imaging lumbar spine (8-2-11) showed a herniated disc at L5-S1 with left foraminal narrowing and annular tears at L3-S1. Electromyography bilateral lower extremities (2013) showed bilateral L4-5 radiculopathy. In a PR-2 dated 2-10-15, the injured worker complained of low back pain with radiation down the right leg, rated 7 out of 10 on the visual analog scale with medications. The treatment plan included refilling medications (Norco, Fentanyl patch, Valium, Ambien, and Prilosec) and a trial of Lidocaine patches. In PR-2's dated 3-10-15, 4-7-15, 6-2-15 and 6-30-15, the injured worker complained of pain to the low back, rated 7 out of 10. In a PR-2 dated 7-28-15, the injured worker complained of more back pain as she had been taking care of her invalid sister. The injured worker reported having persistent low back pain with radiation down the right leg, rated 7 out of 10 on the visual analog scale with medications. Lumbar epidural steroid injections had been approved but the injured worker had been able to get a ride. Physical exam was remarkable for lumbar spine with tenderness to palpation of the L3-5 paraspinal musculature with spasms, tenderness to palpation to bilateral sacroiliac joints, decreased range of motion with extension at 20 degrees, flexion at 50 degrees, bilateral lateral bending at 15 degrees and rotation at 30 degrees, 5 out of 5 bilateral lower extremity motor strength, decreased sensation to the right lower extremity and positive Faber sign. Current diagnoses included lumbar spine radiculopathy, muscle spasms, long-term use of medications, encounter for therapeutic drug monitoring and insomnia. The physician noted that medications helped to control the injured worker's pain. The injured worker was functional, able to perform

activities of daily living and care for her sister. The plan of care consisted of refilling medications (Norco, Omeprazole, Fentanyl patch, Valium, Ambien, Lidocaine patches, Fluriprofen cream Sentra AM, Sentra PM and Theramine) and initiating Lunesta as it lasts longer. On 8-24-15, Utilization Review modified a request for Norco #120 to Norco #90 noting that the injured worker's physical exam was unchanged and the lack of further documentation of the need for more pain medication. Utilization Review denied a request for Lunesta noting lack of documentation regarding the injured worker's insomnia and ambiguity about whether Ambien had been discontinued. Utilization Review noncertified a request for topical Flurbiprofen cream noting lack of documentation of failed first-line therapy and those topical non-steroidal anti-inflammatory medications were not recommended for the spine. Utilization Review noncertified requests for Sentra AM, Sentra PM and Theramine noting that ODG guidelines do not recommend medical foods.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg qid #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, dealing with misuse & addiction, Opioids, differentiation: dependence & addiction, Opioids, indicators for addiction.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. In accordance with California MTUS guidelines, narcotics for chronic pain management should be continued if: "(a) If the patient has returned to work, (b) If the patient has improved functioning and pain." MTUS guidelines also recommends that dosing "not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose." Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Within the documentation available for review, there is no indication that the medication is improving the patient's pain (in terms of percent reduction in pain or reduced NRS), no documentation regarding side effects, and no discussion regarding aberrant use. Therefore, based on the submitted medical documentation, the request for Norco 10/325 is not medically necessary.

Lunesta (Eszopicolone) 2mg, 1/d HS #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter: Eszopicolone (Lunesta), Mental Illnesss & Stress Chapter, Eszopicolone (Lunesta).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress, Zolpidem & Eszopicolone.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of this medication. Per the Official Disability Guidelines (ODG), "Lunesta is not recommended for long-term use." The clinical records submitted do support the fact that this patient has a remote history of insomnia. However, the records do not support the long-term use of this medication for that indication. Specifically, the patient's most recent clinical encounters do not document signs or symptoms of current insomnia. Therefore, based on the submitted medical documentation, the request for Lunesta is not medically necessary.

Medication -Topical fluriprofen creme #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of treatment of this medication for this patient. The California MTUS guidelines address the topic of NSAID prescriptions by stating, "A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics." Furthermore, MTUS guidelines specifically state regarding topical Non-steroidal anti-inflammatory agents (NSAIDs): "The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis 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." This patient has a history of recurrent low back pain. The medical records do not support that the patient has osteoarthritis, or a contraindication to other non-opioid analgesics. Therefore, medical necessity for fluriprofen crème #2 prescription has not been established. The request is not medically necessary.

Sentra AM, BID, #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The Official Disability Guidelines state that Sentra AM is not recommended. Sentra AM is a medical food from [redacted], intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, gingko biloba, and acetyl L-carnitine. There was no rationale submitted in the submitted documentation to indicate the use of Sentra AM other than the patient's chronic pain syndrome. There were no other significant factors provided to justify the use outside of the current guidelines. Given the evidence based guidelines and the lack of submitted documentation, the request would not be indicated. Therefore, based on the submitted medical documentation, the request for Sentra AM is not-medically necessary.

Sentra PM, BID #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter: Sentra PM.

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

Decision rationale: The Official Disability Guidelines state that Sentra PM is not recommended. Sentra PM is a medical food from [redacted], intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, gingko biloba, and acetyl L-carnitine. There was no rationale submitted in the submitted documentation to indicate the use of Sentra PM other than the patient's chronic pain syndrome. There were no other significant factors provided to justify the use outside of the current guidelines. Given the evidence based guidelines and the lack of submitted documentation, the request would not be indicated. Therefore, based on the submitted medical documentation, the request for Sentra PM is not medically necessary.

Medication Theramine TID #180: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter: Theramine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Medications for chronic pain, Introduction.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The California MTUS guidelines and the ACOEM

Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), Theramine is: "Not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytrytophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L- serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%)." This patient has chronic lower back pain secondary to an industrial accident. Per ODG, teramine is specifically not indicated for the treatment of chronic pain. Therefore, based on the submitted medical documentation, the request for theramine is not medically necessary.