MAXIMUS Federal Services

Case Number:	CM14-0059612		
Date Assigned:	07/09/2014	Date of Injury:	04/13/1996
Decision Date:	09/29/2014	UR Denial Date:	03/20/2014
Priority:	Standard	Application Received:	04/28/2014

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 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 53-year-old female who reported an injury on 04/13/1996. The mechanism of injury was not submitted for review. The injured worker has diagnoses of chronic neck pain and lumbar pain, and lumbar disc degeneration. The documentation submitted for review indicates that the injured worker's past treatment consists of the use of TED hose and medication therapy. Medications include baclofen, Savella, Nuedexta, Norco, and Butrans patches. EMG/NCS were done on all 4 extremities. On 03/14/2014, the injured worker complained of extreme pain. Physical examination revealed that the injured worker had a pain rate of 7.5-8 with medication, and without Rx 10/10. There were no ranges of motion, motor strength, or sensory deficits documented in the submitted report on the injured worker's neck or lower back. The treatment plan is for the injured worker to continue such medications. The rationale and Request for Authorization form were not submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Baclofen 10mg #90 x 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines antispasticity drugs Page(s): 64.

Decision rationale: The request for baclofen 10 mg 90 tablets x 2 refills is not medically necessary. According to the MTUS, the mechanism of action of baclofen is blockade of the pre- and postsynaptic GABA receptors. It 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, proximal neuropathic pain (non-FDA approved). Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The request submitted did not specify the duration or frequency of the medication. There was no assessment regarding functional improvement as a result of the medication. In addition, there was no mention of a lack of side effects. Furthermore, it was not noted in the report that the medication was helping with the functional deficits the injured worker had. Given the above, the request is not supported by the California MTUS Guideline recommendations. As such, the request for baclofen 10 mg is not medically necessary.

Savella 50mg #60 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Milnacipran (Savella) Page(s): 62,105..

Decision rationale: The request for Savella 50 mg is not medically necessary. The California MTUS Guidelines do not recommend milnacipran (Savella). It is not FDA-approved and not available in the U.S. at this time. An FDA phase 3 study demonstrated significant therapeutic effects of Savella for treatment of fibromyalgia syndrome. Given that the requested medication is not recommended by the MTUS, the request for Savella is not medically necessary.

Neudexta 10/20 #30 x 2 refills Cervical Spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/nuedexta.html.

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

Decision rationale: The request for Nuedexta 10/20 is not medically necessary. According to the ODG, it is not recommended for conditions. The FDA has approved this treatment for pseudo bulbar affect in adults. PBA is seen in a number of neurologic conditions and is characterized by sudden and uncontrollable bouts of laughing or crying that is either unrelated or disproportionate to the emotional state of the patient. This agent has been studies to date in patients with multiple sclerosis and amyotrophic lateral sclerosis. Although it is not a life-threatening condition, it can have a significant effect on the patient's ability to interact normally in society and in relationships. Nuedexta is not suitable for treating episodes of laughing or crying brought on by mood swings and not due to pseudo bulbar affect. There are no quality

published studies of the off-label use of Nuedexta to treat chronic neuropathic pain. Given the above, the injured worker is not within ODG recommendations. As such, the request for Nuedexta is not medically necessary.

Norco 10/325mg #180 x 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 Norco, On-Going Management, and Opioids for chronic pain Page(s): 75, 78, 80.

Decision rationale: The request for Norco 10/325 is not medically necessary. The California Medical Treatment Utilization Schedule (MTUS) Guidelines state that opioids appear to be efficacious, but limited for short-term pain relief, and long-term efficacy is unclear but also appears limited. Failure to respond to time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There was no evidence to recommend 1 opioid over another. For ongoing management there should be documentation of the 4 A's to include analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behavior. The California MTUS Guidelines also indicate that the use of drug screening is for the patients with documented issues of abuse, addiction, or poor pain control. The MTUS Guidelines also state that an 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 the pain relief lasts. The documentation submitted for review indicated that the Norco was helping the injured worker. However, there was no quantified information regarding pain relief. There was also no assessment regarding current pain on VAS, average pain, intensity of pain, or longevity of pain. There was a lack of documentation regarding consistent urine drug screens. In addition, there was no mention of a lack of side effects. Given the above, the request for Norco is not supported by the California MTUS. Furthermore, the request as submitted did not stipulate a duration or frequency for the medication. As such, the request for Norco 10/325 is not medically necessary.

Butrans Patch 15mg #4 x 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 Buprenorphine (Butrans) Page(s): 26-27.

Decision rationale: The request for Butrans patch is not medically necessary. The California MTUS recommend Butrans for the treatment of opioid addiction and also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction. In recent years, Butrans has been introduced in most European countries as a transdermal formulation (patch) for the treatment of chronic pain. The FDA has only approved

sublingual Subutex and Suboxone. Few studies have been reported on the efficacy of Butrans (buprenorphine), however, it is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected. The submitted reports did not indicate any diagnosis of opioid addiction. Given the guidelines above, the injured worker is not within the MTUS Guideline recommendations. Butrans patch seems to only be available and in use in European countries. Given that it is not FDA-approved, the request for Butrans patch is not medically necessary.