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| Case Number: | CM14-0207501 | | |
| Date Assigned: | 12/19/2014 | Date of Injury: | 09/21/2013 |
| Decision Date: | 02/13/2015 | UR Denial Date: | 11/12/2014 |
| Priority: | Standard | Application Received: | 12/10/2014 |

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 Emergency Medicine, and is licensed to practice in New York. 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 patient is a 64-year-old male who was injured on September 21, 2013. The patient continued to experience pain in his neck, left shoulder, left elbow, left wrist, and low back. Physical examination was notable for tenderness to the occiputs and neck musculature, decreased range of motion of the left shoulder, positive impingement sign of the left shoulder, tenderness to the left lateral epicondyle, tenderness of the left wrist at the carpal tunnel, tenderness at the triangular fibrocartilage complex, 4/5 motor strength in all muscle groups of the bilateral upper extremities, decreased sensation along the median nerve distribution, tenderness to the paralumbar muscles, decreased sensation of the L4, L5, and S1 dermatomes, and 4/5 motor strength in all muscle groups of the bilateral lower extremities. Diagnoses included cervical spine pain, cervical spine radiculopathy, cervical disc displacement, left shoulder sprain/strain, left shoulder internal derangement, left wrist carpal tunnel syndrome, lumbar spine pain, lumbar spine radiculopathy, and lumbar disc displacement. Treatment included medications, physical therapy, and acupuncture. Requests for authorization for Dicopanol, Fanatrex, Synapryn, and Deprizine were submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dicopanol: 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, Insomnia Treatment

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Drugs for Insomnia Treatment Guidelines from The Medical Letter, July1, 2012 (Issue 119) p. 57

Decision rationale: Dicopanol is diphenhydramine, an antihistamine medication, currently approved by the FDA as a "sleep-aid" for sale without a prescription. The medication was prescribed for the treatment of insomnia. Insomnia treatment should be based on etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Antihistamines are sedating, but there is little acceptable evidence that they improve the quality or quantity of sleep. Tolerance to the sedative effects of antihistamines may develop rapidly. They can cause next-day sedation, impairment of performance skills such as driving, and troublesome anticholinergic effects such as dry mouth and urinary retention, which have been associated with cognitive impairment and increased mortality in elderly patients. In this case the diagnosis of insomnia is not supported by the documentation in the medical record. In addition there is risk of adverse effects with little benefit. The request is not medically necessary.

Fanatrex: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16, 18, 19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines. Page(s): 18-19.

Decision rationale: Fanatrex is gabapentin, an anti-epileptic medication. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, and chronic regional pain syndrome. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. In this case the patient has been using the Fanatrex since at least May 2014 and had not obtained analgesia. The request is not medically necessary.

Synapryn: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines. Page(s): 50, 74-96.

Decision rationale: Synapryn is a compounded medication containing tramadol and glucosamine. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDS have failed.. In this case the patient has been using the medication since at least May 2014 and has not obtained analgesia. Tramadol is not recommended. Glucosamine is recommended as an option, in patients with moderate arthritis pain, especially for knee osteoarthritis. Multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee) have been completed and controversy on efficacy related to symptomatic improvement continues. Glucosamine may not be helpful for patients with osteoarthritis of the hip or knee, according to the results of a recent meta-analysis in British Medical Journal, but the authors concluded the medication is not dangerous, and there is no harm in having patients continue the medication as long as they perceive a benefit and cover the costs of treatment themselves. The medication is not covered. The guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains a drug that is not recommended. Therefore the medication cannot be recommended. The request should is not medically necessary.

Deprizine: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68-69.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: The Medical Letter on Drugs and Therapeutics; March 8, 2010 (Issue 1333) p. 17: Primary Prevention of Ulcers in Patients Taking Aspirin or NSAIDs

Decision rationale: Deprizine is ranitidine, an H2-receptor antagonist. It is indicated for the treatment of peptic ulcer disease and been shown to prevent NSAID-related gastric ulcers in high doses. In this case the patient did not have diagnosis of ulcer disease. The patient did not have

any complaint of nausea or dyspepsia. Medical necessity has not been established. The request is not medically necessary.