MAXIMUS Federal Services

Case Number:	CM13-0056001		
Date Assigned:	12/30/2013	Date of Injury:	11/12/2010
Decision Date:	05/27/2014	UR Denial Date:	10/23/2013
Priority:	Standard	Application Received:	11/21/2013

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 Anesthesilogy, 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 63-year-old male who reported an injury on 11/12/2010. The mechanism of injury was cumulative trauma. The medication history included topical creams, PPIs, muscle relaxants, opiates, NSAIDs, and medications for constipation. The documentation of 09/17/2013 revealed the injured worker's pain was a 3-5/10. The diagnoses included cervical spine disc syndrome, bilateral shoulder rotator cuff syndrome, right shoulder internal derangement, low back syndrome, lumbar spine herniated nucleus pulposus, and bilateral lower extremity radiculitis. The treatment plan included Prilosec #30 20 mg twice a day to protect the stomach, tramadol ER 150 mg #30 once a day to reduce pain, refill of TG-Hot and Fluriflex topical creams, an internal medicine special, and a return visit. The treatment plan also included Senna and a urine toxicology screen.

IMR ISSUES, DECISIONS AND RATIONALES

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

TRAMADOL ER 150MG #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: Chronic Pain Medical Treatment Guidelines, Tramadol (Ultram, generic available).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Ongoing Management Page(s): 60, 78.

Decision rationale: The California MTUS Guidelines recommend opiates for chronic pain. There should be documentation of objective improvement, objective decrease in pain, and documentation that the injured worker is being monitored for aberrant drug behavior and side effects. The injured worker had been utilizing the medication for more than 6 months. The clinical documentation submitted for review indicated the injured worker was being monitored for aberrant behavior through urine drug screens. There was lack of documentation of objective functional benefit, and an objective decrease in pain with the medication, as well as side effects. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for tramadol ER 150 mg is not medically necessary.

A REFILL OF TGHOT TOPICAL CREAM: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol; Gabapentin; Topical Capsaicin; Topical Analgesics; Topical Salicylates Page(s): 82; 11. Decision based on Non-MTUS Citation FDA.gov.

Decision rationale: The California MTUS indicated that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended, Topical Salicylates are recommended. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy, Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 6 months. There was lack of documentation of objective functional improvement and an objective decrease in pain. The clinical documentation failed to indicate the injured worker had neuropathic pain. The request as submitted failed to indicate the frequency, quantity, and strength for the requested medication. Given the above, the request for a refill of TG-Hot topical cream is not medically necessary.

A REFILL OF FLURFLEX TOPICAL CREAM: 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 Flurbiprofen; Topical Analgesics; Cyclobenzaprine Page(s): 72; 111; 41.

Decision rationale: California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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 agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 6 months. There was a lack of documentation of objective functional benefit. There was lack of documentation indicating the injured worker had neuropathic pain. The request as submitted failed to indicate the frequency, quantity, and strength for the medication. Given the above, the request for a refill of Fluriflex topical cream is not medically necessary.

A REFILL OF SENNA PLUS: 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 Initiation of Opioid Therapy Page(s): 77.

Decision rationale: The California MTUS Guidelines recommend that when initiating opioid therapy, prophylactic treatment of constipation should be initiated. The clinical documentation submitted for review indicated the injured worker had been utilizing the class of medication for more than 6 months. There was lack of documentation of objective functional benefit. The request as submitted failed to indicate the frequency, quantity, and strength for the requested medication. Given the above, the request for a refill of Senna Plus is not medically necessary.

PRILOSEC 20MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Page(s): 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69.

Decision rationale: The California MTUS Guidelines recommend PPIs for the treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the physician was prescribing the medication for gastric protection. However, the clinical documentation indicated the injured worker had utilized the medication for greater than 6

months and there was a lack of documentation of efficacy for the requested medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Prilosec 20 mg #30 is not medically necessary.