MAXIMUS Federal Services

Case Number:	CM13-0027889		
Date Assigned:	11/22/2013	Date of Injury:	07/17/2002
Decision Date:	02/11/2014	UR Denial Date:	08/23/2013
Priority:	Standard	Application Received:	09/23/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Oklahoma and Texas. 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 physician 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:

This patient is a 61-year-old female who reported an injury on 07/17/2002. The documentation submitted for review indicates that this patient is currently diagnosed with chronic regional pain syndrome over the right upper extremity status post right medial epicondylectomy and cubital tunnel release. The patient is also status post right carpal tunnel release and left cubital tunnel release. Notes indicate that the patient has a disability precluding forceful strength activities and repetitive manipulation of the bilateral upper extremities and is precluded from repetitive motion of the neck. The current request for consideration is for medications to include Savella 100 mg, Aciphex 20 mg, and Flector patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 100 mg #60: Upheld

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

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

Decision rationale: The California MTUS states that Milnacipran is not recommended as it is not FDA approved and not available in the US at this time. Milnacipran is under study as a treatment for fibromyalgia syndrome. An FDA Phase III study demonstrated "significant therapeutic effects" of Milnacipran for treatment of fibromyalgia syndrome. Milnacipran (San Diego's Cypress Bioscience Inc.) has been approved for the treatment of depression outside of the U.S. and is in a new class of antidepressants known as Norepinephrine Serotonin Reuptake Inhibitors. Long-term effectiveness of anti-depressants has not been established. Based on the recommendation of the guidelines, this medication is indicated for the treatment of fibromyalgia syndrome. The patient is not diagnosed currently with fibromyalgia syndrome. Furthermore, there is indication in the guidelines that this medication is currently not FDA-approved for use. Additionally, there is a discrepancy in the submitted clinical notes with treatment notes on 11/07/2013 indicated that the patient is currently prescribed Savella 150 mg for use twice daily; however, the current request is for Savella 100 mg #60. Given the above, the request for Savella 100 mg #60 is not medically necessary and appropriate.

Aciphex 20 mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Section Page(s): 68.

Decision rationale: The California MTUS states that patients at intermediate risk for gastrointestinal events and no cardiovascular disease should consider use of a non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily or a medication such as misoprostol (200 Î¼g four times daily); or use of a Cox-2 selective agent. Caution is given with long-term use of proton pump inhibitors as studies of use of PPI's show that use for (> 1 year) has increased the risk of hip fracture. The documentation submitted for review indicates that the patient is currently prescribed Aciphex oral tablet delayed release 20 mg as part of her medication regimen. Furthermore, clinical notes submitted for review indicates that the patient has a history of gastroesophageal reflux disease as a result of chronic opioid use. However, there is no clear indication in the notes of a history of ulcers or gastrointestinal bleeding. Additionally, there is no clear indication in the notes of current GI symptoms to support the recommendation for the use of Aciphex. Given the above, the request for Aciphex 20 mg #30 is not medically necessary and appropriate.

Flector patches #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 111-113.

Decision rationale: The California MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. CA MTUS states VoltarenÂ® Gel 1% (Diclofenac) is an FDA-approved agent indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). CA MTUS states Non-steroidal anti-inflammatory agents have limited demonstrated efficacy in clinical trials and have been inconsistent with most studies being small and of short duration. They have been found in studies 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. However, again the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. Documentation submitted for review indicates that the patient is currently prescribed Flector patches as part of her medication regimen. However, based on recommendation of the guidelines, there is only limited demonstrated efficacy in clinical trials, with primary benefit indicated in the first 2 weeks of treatment. While topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks, the most recent clinical notes submitted for review failed to indicate any demonstrated efficacy with the use of Flector patches. Furthermore, there is no clinical documentation indicating that the patient has preclusion for the use of oral nonsteroidal anti-inflammatory medications; and in fact, details that the patient has significant benefit and effect from prior use of oral medications. Given the above, the request for Flector patches #30 is not medically necessary and appropriate.