MAXIMUS Federal Services

Case Number:	CM13-0061502		
Date Assigned:	12/30/2013	Date of Injury:	06/14/2012
Decision Date:	07/29/2014	UR Denial Date:	11/22/2013
Priority:	Standard	Application Received:	12/05/2013

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 Family Practice, and is licensed to practice in California. 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:

This 58 year old male claimant sustained a work injury on 6/14/12 involving the low back. He has a diagnosis of chronic low back and cervical pain with radiculopathy. An MRI on 8/3/12 indicated bilateral facet capsulitis and right annular tear at the L5-S1 level. He underwent a microdiskectomy in March 2013. There are no other non-industrial related diagnoses. A progress note on 11/13/13 indicated the claimant has 5/10 pain and has stopped taking opioids. Physical findings were notable for tenderness in the paracervical region and paralumbar region along with restricted range of motion. His sleep quality was good. His pain had been managed with Flexeril 10mg twice a day and Celebrex 200mg once a day. He had been additionally managed with Ambien 10 mg at night for sleep difficulties. He was continued on his Flexeril and Celebrex, and was prescribed a tapering dose of Ambien. He had been on Flexeril since at least January 2013. He had been on Ambien since May 2013 for poor sleep quality. Prior to this he was on Rozarem for sleep which was ineffective. He had been on Celebrex since June 2013 along with Vicodin after which he was weaned off Vicodin by November 2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ambien 10mg #10: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

Decision rationale: According to the Official Disabiltiy Guidelines on insomnia pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7-10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific components of insomnia should be addressed, including: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; and (d) Next-day functioning. There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin & melatonin receptor agonists; and (4) Over-the-counter medications. The majority of studies have only evaluated the short-term treatment (i.e. 4 weeks) of insomnia; therefore, more studies are necessary to evaluate the efficacy and safety of treatments for long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e., severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance, avoid residual effects and increase next-day functioning. Zolpidem (Ambien) is indicated for the short-term treatment of insomnia with difficulty of sleep onset (7-10 days). Ambien CR is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. Longer-term studies have found Ambien CR to be effective for up to 24 weeks in adults. The extended-release dual-layer tablet (Ambien CR) has a biphasic release system: an initial release of zolpidem reduces sleep latency and a delayed release facilitates sleep maintenance. In this case, the claimant had been on Ambien for five months. This is beyond the short -term use recommended by the guidelines. In addition, the etiology of the sleep disturbance was not clearly defined- whether it was initiating or falling asleep. No evaluation was performed to determine a primary or secondary etiology for insomnia. There is also no indication for weaning down to 10 tablets per month. The Ambien as prescribed is not medically necessary.

Celebrex 200mg #30: Upheld

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

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

Decision rationale: According to the MTUS guidelines, clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Risk factors include: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Patients with no risk factors and no cardiovascular disease do not require a proton pump inhibitor. Patients at intermediate risk for gastrointestinal events and no cardiovascular disease have the option of obtaining: (1) A non-selective NSAID with either a

PPI (Proton Pump Inhibitor), for example, omeprazole or misoprostol or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. Patients at high risk for gastrointestinal events with no cardiovascular disease should use a Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease should take a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. In this case, there is no indication that the claimant has failed tradition NSAID use. In addition, there is no mention of gastrointestinal risks precluding NSAID use. Therefore, the use of Celebrex (a Cox inhibitor) is not medically necessary.

Flexeril 10mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41.

Decision rationale: According to the MTUS guidelines, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Flexeril) is more effective than placebo for back pain. It is recommended for short course therapy and has the greatest benefit in the first four days, suggesting that shorter courses may be better. The addition of cyclobenzaprine to other agents is not recommended. In this case, the claimant was using Flexeril with Celebrex. In addition, the claimant had been on Flexeril for at least 11 months. This is beyond a short-term use. The continued use of Flexeril is not medically necessary.