

Case Number:	CM15-0179280		
Date Assigned:	09/29/2015	Date of Injury:	07/08/2014
Decision Date:	11/09/2015	UR Denial Date:	09/01/2015
Priority:	Standard	Application Received:	09/11/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Family Practice

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 49 year old female, who sustained an industrial injury on 07-08-2014. The injured worker is currently able to work four hours a day. Medical records indicated that the injured worker is undergoing treatment for right medial and lateral epicondylitis and status post right ulnar nerve release. Treatment and diagnostics to date has included TENS (Transcutaneous Electrical Nerve Stimulation) Unit, acupuncture, physical therapy, home exercise program, and medications. Current medications include Neurontin (600mg four times a day), Zoloft, Florastor (250mg #60 1 by mouth twice a day for gastrointestinal effects of Norco), Hydrocodone, Sonata, Zofran, and Pericolace. According to progress note dated 07-30-2015, prior electromyography- nerve conduction velocity studies in fall of 2014 were "within normal limits". After review of progress notes dated 07-28-2015 and 08-18-2015, the injured worker reported right upper extremity pain and stated she "has more pain in her right arm the past couple of weeks". Objective findings included right upper extremity sensitivity. The treating physician noted increasing the Hydrocodone to 5-325mg #180, 1 by mouth 1-6 times a day as needed for pain (per 08-18-2015 note). The Utilization Review with a decision date of 08-21-2015 non-certified the request for Gabapentin 600mg and Florastor 250mg and modified the request for Hydrocodone-Acetaminophen 5-325mg #120 to Hydrocodone-Acetaminophen 5-325mg #60 for weaning.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 600 mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of antiepilepsy drugs such as gabapentin as a treatment modality. In general, medications such as gabapentin are considered as first-line agents for the treatment of neuropathic pain. However, when an anti-epilepsy drug such as gabapentin is used, its long-term use is dependent on documented outcomes provided in the medical records. These MTUS guidelines state the following regarding these relevant outcomes: "Good" response to the use of AED's has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. In this case, there is insufficient documentation in the medical records to indicate that this patient has achieved a significant reduction in pain and an improvement in function. Further, that the use of gabapentin has been associated with a diminished need for other pain medications. For this reason, gabapentin 600 mg is not medically necessary.

Florastor 250 mg: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Opioids, Section: Opioid Induced Constipation.

Decision rationale: The Official Disability Guidelines comment on the treatment of opioid-induced constipation. In the section, if prescribing opioids has been determined to be appropriate, then ODG recommends that prophylactic treatment of constipation should be initiated. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives

may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for non-cancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. In this case, the request is for Florastor, which is in the category of a "probiotic." The specific agent is *saccharomyces boulardi*. A Pubmed search on Florastor indicates that the majority of research on this medication is primarily focused on the treatment of antibiotic associated diarrhea; not opioid-induced gastrointestinal side effects. Given the above ODG recommendations for the treatment of opioid induced constipation and the lack of evidence associating the use of the probiotic *saccharomyces boulardi* with the treatment of opioid side effects, the use of Florastor is not medically necessary.