

<b>Case Number:</b>	CM14-0079953		
<b>Date Assigned:</b>	07/18/2014	<b>Date of Injury:</b>	10/21/2010
<b>Decision Date:</b>	08/15/2014	<b>UR Denial Date:</b>	04/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/30/2014

### 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 Anesthesia, has a subspecialty in Acupuncture and Pain Medicine, 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 is a 37 year old female injured worker with date of injury 10/21/10 with related cervical spine and bilateral upper extremity pain. Per progress report dated 2/4/14, tenderness at the medial aspect of the elbow with subluxation of the ulnar nerve was noted. Per physical exam, there was tenderness at the cervical paravertebral muscles and upper trapezius muscles with spasm. Axial loading compression test and Spurling's maneuver were positive. There was dysesthesia at the C5 and C6 dermatomes. In the left shoulder there was tenderness anteriorly, a positive impingement and Hawkin's sign. Imaging studies were not available in the documentation submitted for review. Per 10/22/13 note, the injured worker was diagnosed with narcotic-induced constipation. Per that note, which was not entirely legible, she stated that lactulose had been helping her with bowel movement, and Linzess had been helping. Treatment to date has included physical therapy and medication management.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lactulose 10gm /15mg solution (quantity 473):** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) TWC Pain Procedure Summary.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines.

**Decision rationale:** Per the MTUS Chronic Pain Medical Treatment Guidelines, when initiating opioid therapy, prophylactic treatment of constipation should be initiated. Specifically regarding treatment, per the Official Disability Guidelines (ODG), when prescribing an opioid, 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. The ODG formulary contains no medications for the treatment of constipation. Considering that lactulose is an over the counter laxative used for the treatment of constipation, it is medically appropriate. The request is medically necessary.

**Linzess 290mcg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) TWC Pain Procedure Summary.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines, [ncbi.nlm.nih.gov/pubmedhealth/](http://ncbi.nlm.nih.gov/pubmedhealth/).

**Decision rationale:** Per the MTUS Chronic Pain Medical Treatment Guidelines, when initiating opioid therapy, prophylactic treatment of constipation should be initiated. Specifically regarding treatment, per the Official Disability Guidelines (ODG), when prescribing an opioid, 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. 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 don't 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 noncancer-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 noncancer-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. Linzess is used to treat irritable bowel syndrome with constipation. It is also used to treat chronic idiopathic constipation. Linzess is not indicated for opioid induced constipation. The use of Linzess is not consistent with the guidelines. The request is not medically necessary.