

<b>Case Number:</b>	CM14-0217885		
<b>Date Assigned:</b>	01/07/2015	<b>Date of Injury:</b>	09/23/2009
<b>Decision Date:</b>	03/05/2015	<b>UR Denial Date:</b>	12/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/29/2014

### 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. 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: New York, Tennessee

Certification(s)/Specialty: Emergency Medicine

### 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 was 54 year old male, who was injured on the job, September 23, 2009. The injured worker last worked September 23, 2009. The injured worker was diagnosed with failed cervical spine surgery secondary to traumatic injury with myelomalacia, lumbar sprain, left frozen shoulder syndrome secondary to shoulder sprain and inactivity. According to the progress note of July 9, 2014, the injured worker has constant neck pain. The pain was associated with bilateral occipital and bilateral frontal headaches. The injured worker describes the pain as aching and severe in severity. The lower back pain is constant and radiates down both lower extremities. The injured worker denies numbness, tinging or weakness to the lower extremities. The pain was aggravated by activity, bending, prolonged sitting, standing, and twisting. The injured worker also reported difficulty sleeping. The injured worker rated pain 5 out of 10 with pain medication and 10 out of 10 without pain medication; 0 being no pain and 10 being the worse pain. The injured worker had tried conservative treatment medication giving temporary relief, physical therapy with limited benefit, acupuncture with limited benefit and cervical epidural injections with limited relief. The physical exam noted limited range of motion to the cervical spine with decrease sensation to the left upper extremity. The lumbar spine had moderately to severe limitations. Pain was significantly increased with flexion and extension. According to the progress note of August 6, 2014, pain level with pain medication was 6 out of 10 and without pain medication 9 out of 10. The injured worker was using a TENS unit along with pain medication which was help, according to the injured worker. The injured worker was continuing a home exercise program. The progress note of September 3, 2014, report pain level

increased to 8 out of 10 with pain medication and 10 out of 10 without, limiting activities of daily living. Review of body systems was negative. The injured worker reported constipation issues; Senna-lax one tablet 2 times daily, was suggested. The progress note of October 15, 2014, the injured worker continues with constipation issues, no change in medication for constipation. The [progress note of December 10, 2014, the injured workers pain level was 8 out of 10 with pain medication and 10 out of ten with pain medication. The injured worker had continued complaints of sleeplessness and constipation. Pain medication was morphine sulfate 15mg three times daily and Senna-lax 1 tablet 2 times daily and Linzess 1 capsule daily was added. According to the progress notes provided for review, the pain medications have not changed in frequency or amount since before July 9, 2014 through December 10, 2014. On December 24, 2014, the UR modified a prescription for Morphine Sulfate 15mg #90 to #75 and denied authorization for prescription and Linzess 145mg #30. The modification of the Morphine Sulfate was based on the MTUS guidelines for long term treatment of chronic nonmalignant pain with opioids. If prescribed for long term use periodic evaluation must demonstrate on going effectiveness in controlling pain, improving function and quality of life, no intolerable side effects and no aberrant drug taking behavior. The denial for linzess was based on the ODG guidelines recommend a stepwise approach to treating opioid-induced constipation. The first step was lifestyle modifications and if needed over-the-counter stool softener and laxatives, if not effective prescription drugs are recommended.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 prescription of Morphine Sulfate 15mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use; weaning of medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96.

**Decision rationale:** Morphine is an opioid medication. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDS have failed. In this case the patient has been taking Morphine since at least July 2014 and has not obtained analgesia. Criteria for long-term opioid use have not been met. The request should not be authorized.

#### **1 prescription of Linzess 145mcg #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), Pain (Acute & Chronic), Opioid-induced constipation treatment

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Opioid-induced constipation treatment Linaclotide (Linzess) for Constipation The Medical Letter on Drugs and Therapeutics - November 12, 2012 (Issue 1403)

**Decision rationale:** Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. If prescribing opioids has been determined to be appropriate, then ODG recommend 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 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. Second line options include methylnaltrexone and lubiprostone. Linzess is linaclotide, a medication used for the treatment of constipation. It is a synthetic peptide that increases the secretion of chloride and bicarbonate ions into the intestinal lumen, increasing intraluminal fluid and accelerating intestinal transit. The most common adverse effects of linaclotide have been diarrhea, abdominal pain, flatulence, and abdominal distension. Linaclotide (Linzess) has been effective in increasing the number of bowel movements and decreasing abdominal pain in a small percentage of patients with chronic idiopathic constipation or irritable bowel syndrome with constipation. How it compares to lubiprostone remains to be determined. The long-term safety and effectiveness of both linaclotide and lubiprostone are unknown. In this case there is no documentation that the patient has tried and failed first-line treatments such as increasing physical activity and maintaining appropriate hydration. There is no documentation that the patient has tried and failed other over the counter treatments such as polyethylene glycol or milk of magnesia. ODG does not comment on Linzess and recommends methylnaltrexone and lubiprostone as second line agents. Medical necessity has not been established. The request should not be authorized.

