

<b>Case Number:</b>	CM15-0218195		
<b>Date Assigned:</b>	11/10/2015	<b>Date of Injury:</b>	10/05/2001
<b>Decision Date:</b>	12/28/2015	<b>UR Denial Date:</b>	10/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/05/2015

### 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: Iowa, Illinois, California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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:

This is a 57 year old male with a date of injury of October 5, 2001. A review of the medical records indicates that the injured worker is undergoing treatment secondary gastroesophageal reflux disease and stomach upset due to chronic use of pain medications and anti-inflammatory medications. Medical records dated August 18, 2015 indicate that the injured worker complained of difficulty getting opioid pain medications, and that he hadn't been taking them. The physical exam did not document any findings regarding the injured worker's abdomen or gastrointestinal system. Treatment has included hernia surgery (March of 2015) and medications (Linzess noted on August 19, 2015; Norco, Lunesta, Zegrid, and Xanax). The utilization review (October 7, 2015) non-certified a request for Linzess 145mcg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Linzess Cap 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 (Chapter), Opioids, criteria for use.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioid-induced constipation treatment and Other Medical Treatment Guidelines Uptodate, Management of chronic constipation in adults.

**Decision rationale:** ODG states that first line treatment should include physical activity, appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber and 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. According to UpToDate, patients who do not tolerate bulk-forming laxatives or respond poorly to fiber, we suggest an osmotic laxative next if tolerated (Grade 2C). Other options include stool softeners, stimulant laxatives (bisacodyl, senna, and sodium picosulfate), and secretory agents (lubiprostone, linaclotide). UpToDate also states that Linaclotide is a minimally absorbed peptide agonist of the guanylate cyclase-C receptor that stimulates intestinal fluid secretion and transit. Linaclotide has been approved by the US Food and Drug Administration for the treatment of chronic idiopathic constipation at a dose of 145 micrograms daily [32]. However, the role of Linaclotide in treating chronic constipation and the long-term risks and benefits remain to be determined. The treating physician did document constipation side effects of opioid usage, but does not document attempt of the first line treatment mentioned above and the results of those treatments. Additionally, no quantitative or qualitative description of bowel movement frequency/difficulty was provided either pre or post constipation treatment education by the physician, which is important to understand if first line constipation treatment was successful. As such, the request for Linzess Cap 145mcg #30 is not medically necessary.