

<b>Case Number:</b>	CM15-0138388		
<b>Date Assigned:</b>	07/28/2015	<b>Date of Injury:</b>	05/11/2006
<b>Decision Date:</b>	08/28/2015	<b>UR Denial Date:</b>	06/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/16/2015

### 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: Texas, New York, California  
 Certification(s)/Specialty: Preventive Medicine, Occupational 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 applicant is a represented 44-year-old who has filed a claim for chronic low back pain (LBP) reportedly associated with an industrial injury of May 11, 2006. In a utilization review report dated June 19, 2015, the claims administrator failed to approve a request for Linzess. The claims administrator referenced a June 11, 2015 RFA form and an associated office visit of the same date in its determination. On July 20, 2015, the applicant reported ongoing complaints of low back pain with ancillary complaints of opioid-induced constipation. 7/10 low back pain complaints were reported with associated radiation of pain into the left leg. The applicant was on Norco, Duragesic, and Lyrica, it was reported. The applicant was using a cane to move about. It was suggested that the applicant was in fact working. It was suggested in one section of the note that the applicant was "not disabled," suggesting that the applicant was currently working. The applicant was given refills of Duragesic, Lyrica, and Norco. On June 11, 2015, the applicant reported ongoing complaints of low back pain. On this date, Linzess was introduced. Norco 5/325 was prescribed.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Linzess 290mcg #30 with 3 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management Page(s): 7-8. Decision based on Non-MTUS Citation U. S. Food and Drug Administration. INDICATIONS AND USAGE LINZESS is a guanylate cyclase-C agonist indicated in adults for treatment of: Irritable bowel syndrome with constipation (IBS-C) (1. 1). Chronic idiopathic constipation (CIC) (1. 2).

**Decision rationale:** No, the request for Linzess, a laxative agent, was not medically necessary, medically appropriate, or indicated here. While page 77 of the MTUS Chronic Pain Medical Treatment Guidelines does support the prophylactic treatment of constipation in applicants using opioids, this recommendation is, however, qualified by commentary made on pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines to the effect that an attending provider using a drug for non-FDA-labeled purposes has the responsibility to be well informed regarding usage of the same and should, furthermore, furnish compelling evidence to support such usage. The Food and Drug Administration (FDA) notes that Linzess is indicated in the treatment of chronic idiopathic constipation and/or irritable bowel syndrome-induced constipation. The FDA does not, thus, establish a role for usage of Linzess for the opioid-induced constipation present here. The attending provider reported on July 20, 2015 that the applicant had issues with opioid-induced constipation, i.e., an issue for which Linzess is not endorsed by the FDA. The attending provider did not, furthermore, furnish a clear or compelling rationale and/or medical evidence to support such usage in the face of the unfavorable FDA position on the same via his progress notes of July 20, 2015 or June 11, 2015, referenced above. Therefore, the request was not medically necessary.