

<b>Case Number:</b>	CM15-0109241		
<b>Date Assigned:</b>	06/15/2015	<b>Date of Injury:</b>	07/23/2003
<b>Decision Date:</b>	07/16/2015	<b>UR Denial Date:</b>	05/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/05/2015

### 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: 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:

This is a 52 year old female injured at work on July 23, 2003. Diagnoses were noted to be right shoulder derangement, major depressive disorder, single episode, unspecified; and generalized anxiety disorder; psychological factors affecting medical condition. Treatments to date have included medications and psychotherapy. Present medications include Effexor, Seroquel, Xanax, Restoril, Percocet, Celebrex, Butrans patch, orphenadrine and capsaicin. A progress note dated April 22, 2015 documents subjective findings of depression; change in appetite; lack of motivation; difficulty getting to sleep; difficulty staying asleep; decreased energy; emptiness and inadequacy; difficulty thinking; weight loss; restlessness; agitation; panic attacks; inability to relax; shaking; flashbacks; tension headaches; increased pain; abdominal pain/cramping; constipation or diarrhea, and objective findings of visible anxiety; depressed facial expressions. The treating physician requested authorization for a prescription for Linzess.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription of Linzess 145mg #15 with 2 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Gastroenterological Association,

Bharucha AE, Dorn, SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013 Jan; 144(1):211-7.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation 1) American Gastroenterological Association Medical Position Statement on Constipation, *Gastroenterology*, Volume 144, Issue 1, Pages 211-217, January 2013. 2) University of Iowa College of Nursing Guideline: Management of Constipation, 1996 (revised 2009 Oct). Bibliographic Source(s): McKay SL, Fravel M, Scanlon C. Management of constipation. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51 p. [44 references] 3) FDA approves Linzess to treat certain cases of irritable bowel syndrome and constipation. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm317505.htm>.

**Decision rationale:** Linzess (linaclotide) is a chloride channel stimulator medication approved to treat chronic idiopathic constipation and to treat irritable bowel syndrome with constipation (IBS-C) in adults. The MTUS does not comment on use of Linzess. The common causes of chronic constipation in this patient's age group are inadequate fiber in diet, inadequate fluid intake, inadequate exercise and/or side effects from medications (such as opioids). Medical treatment would normally begin with fiber supplementation and/or osmotic or stimulant laxatives. The patient is on a number of medications for which the opioids, Percocet and the Butrans patch, are known to commonly cause constipation. It is assumed that this is the reason for the request for use of Linzess. However, the treatment for opioid-induced constipation is a stool softener plus a stimulant laxative. Linzess does not work in this manner. The patient has not been diagnosed with chronic idiopathic constipation or irritable bowel syndrome with constipation. At this point in the care of this patient there is no indication to use this medication. The request is not medically necessary.