

<b>Case Number:</b>	CM14-0201728		
<b>Date Assigned:</b>	12/12/2014	<b>Date of Injury:</b>	03/29/1996
<b>Decision Date:</b>	01/30/2015	<b>UR Denial Date:</b>	11/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/02/2014

### 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 Occupational 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:

The applicant is a represented [REDACTED] employee who has filed a claim for chronic low back pain reportedly associated with an industrial injury of March 29, 1996. In a Utilization Review Report dated November 26, 2014, the claims administrator partially approved a request for Linzess. A November 19, 2014 progress note was referenced. The claims administrator contended that the applicant had been using various laxatives and stool softeners for over 15 years. The claims administrator contended that the attending provider had not outlined whether or not ongoing usage of Linzess had or not had not proven beneficial here. The applicant's attorney subsequently appealed. In a handwritten progress note dated October 6, 2014, the applicant was placed off of work, on total temporary disability. OxyContin, Neurontin, Amitiza, Percocet, and Topamax were renewed while the applicant was kept off of work. In a narrative report of the same date, October 2014, the applicant was described as having used the same medication regimen for 15 years after failed lumbar spine surgery. 6 to 7/10 pain was noted. The attending provider posited that the applicant was trying to be active during the day with medications. The applicant's medication list included Cymbalta, OxyContin, Percocet, Reglan, Skelaxin, Topamax, and Senna, it was stated toward the top of the report. The applicant did have comorbid diabetes and was apparently using metformin and glipizide stated in another section of the note. The applicant was overweight, with a BMI of 30. Multiple medications were renewed at the bottom of the report, including OxyContin, Amitiza, Percocet, Skelaxin, and Topamax. In an earlier handwritten note dated August 4, 2014, the applicant was placed off of work, on total temporary disability. In a narrative report of the same date of August 4, 2014, it was again stated that the applicant had been on the current medications for 15 years. Persistent complaints of back and leg pain were noted. The applicant was described as using Senna, a laxative agent, toward the top of the report. The applicant stated diagnoses included myofascial pain syndrome,

chronic low back pain, depression, and failed lumbar spine surgery. OxyContin, Percocet, Skelaxin, and Topamax were endorsed towards the bottom of the report. On November 19, 2014, the applicant reported persistent complaints of low back pain. The applicant was using OxyContin thrice daily and Percocet twice daily and Skelaxin four times daily. The applicant was also using Skelaxin for depression. The applicant's medication list stated somewhat incongruously in different sections of the report. In one section of the note, it was stated the applicant was using Amitiza, Cymbalta, OxyContin, Percocet, Reglan, Skelaxin, Topamax, and Senna. A second section of the note stated the applicant was using Skelaxin, aspirin, Tenormin, glipizide, glucosamine, Zestoretic, metformin, Reglan, Protonix, Senna, and Zocor. Finally, at the bottom of the report, the applicant was given prescription for Linzess, Percocet, and OxyContin. It was stated that Linzess was being endorsed for opioid-induced constipation on the grounds that the applicant had failed other stool softeners and laxatives including Amitiza, Dulcolax, and Senna.

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

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

**Linzess 145mcg #30 with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management Initiating Therapy Page(s): 7-8; 77. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), Linzess Medication.

**Decision rationale:** 1. 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 prophylactic administration of laxative in applicants using opioids agents, this recommendation, however, is qualified by commentary made on page 7 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 medical evidence to support such usage. The Food and Drug Administration (FDA), however, notes that Linzess is indicated in the treatment of irritable bowel syndrome and constipation and/or in the treatment of chronic idiopathic constipation. Linzess, thus, is not indicated in the treatment of opioid-induced constipation as was/is present here. The attending provider did not furnish any compelling medical evidence which would support provision of Linzess in the clinical context present here. Therefore, the request was not medically necessary.