MAXIMUS Federal Services

Case Number:	CM15-0204275		
Date Assigned:	10/21/2015	Date of Injury:	06/30/2000
Decision Date:	12/08/2015	UR Denial Date:	09/24/2015
Priority:	Standard	Application Received:	10/19/2015

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 [redacted] beneficiary who has filed a claim for chronic neck pain reportedly associated with an industrial injury of June 30, 2000. In a Utilization Review report dated September 24, 2015, the claims administrator failed to approve requests for Linzess. The claims administrator referenced a September 9, 2015 office visit in its determination. The applicant's attorney subsequently appealed. On September 11, 2015, the applicant reported ongoing issues with chronic neck pain. The applicant was using Norco, Desyrel, Neurontin, Zofran, Colace, and Linzess, the treating provider reported. The claimant was using both Colace and Linzess for constipation associated with opioids, it was reported. Multiple medications were renewed as were the applicant's permanent work restrictions. It was not clearly stated whether the applicant was or was not working with limitations in place, although this did not appear to be the case.

IMR ISSUES, DECISIONS AND RATIONALES

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

Linzess 145 MCG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Introduction. Decision based on Non-MTUS Citation U.S. Food and Drug Administration 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. Pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines stipulate that an attending provider using a drug for non-FDA labeled purposes has the responsibility to be well-informed regarding the usage of the same and should, furthermore, compelling evidence to support such usage. The Food and Drug Administration (FDA) notes, however, the Linzess is indicated in the treatment of chronic idiopathic constipation and/or constipation due to irritable bowel syndrome. Here, however, the attending provider indicated that Linzess is being employed for a non-FDA labeled purpose, i.e., for opioid-induced constipation. The attending provider failed to furnish a clear or compelling rationale or medical evidence, which would support such usage in the face of the unfavorable FDA position on the same. Therefore, the request is not medically necessary.