

<b>Case Number:</b>	CM15-0024552		
<b>Date Assigned:</b>	02/17/2015	<b>Date of Injury:</b>	11/03/2002
<b>Decision Date:</b>	07/15/2015	<b>UR Denial Date:</b>	01/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/09/2015

### 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: Pennsylvania

Certification(s)/Specialty: Internal Medicine, Hospice & Palliative 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 injured worker is a 62 year old male, who sustained an industrial injury on 11/3/02. The injured worker was diagnosed as having severe degenerative disc disease, discogenic disease, and stenosis of the lumbar spine at L4-5 and L5-S1 associated with bilateral lower extremity radiculitis. Other diagnoses included degenerative disc disease and presumed discogenic disease at L1-4, degenerative lumbar/lumbosacral intervertebral disc, lumbar region spinal stenosis, and thoracic/lumbar neuritis/radiculitis. Constipation with medication was also noted. Treatment to date has included posterior lumbar fusion at L4-5 and L5-S1 in January 2008, removal of hardware on 5/29/09, spinal cord stimulator implantation on 3/14/14, and medication. The injured worker had been taking Linzess since at least 12/4/13. Currently, the injured worker complains of low back pain and bilateral leg pain and weakness. The treating physician requested authorization for Linzess (linaciotide) 290g #30 and PC 5001 150g

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Linzess (linaciotide) 290 ugm, one qd prn #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Linaclotide: Drug Information. Topic 86369, version 51.0. UpToDate, accessed 07/12/2015.

**Decision rationale:** Linzess (linaclotide) is a medication. The MTUS Guidelines are silent on this issue. Linaclotide is FDA-approved for the treatment of chronic constipation due to unknown causes at the 145mcg dose and for irritable bowel syndrome with constipation at the 290mcg dose. The submitted and reviewed documentation indicated the worker was experiencing pain in the lower back that went into both legs with weakness, numbness, and tingling; problems sleeping; fatigue; and constipation due to pain medication. There was no discussion indicating the worker had irritable bowel syndrome with constipation or describing special circumstances that sufficiently supported this request. In the absence of such evidence, the current request for 30 tablets of Linzess (linaclotide) 290mcg taken one tablet daily as needed is not medically necessary.

**PC 5001 (unspecified) 150gm:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The MTUS Guidelines are silent on the issue of PC 5001. The submitted and reviewed documentation indicated the worker was experiencing pain in the lower back that went into both legs with weakness, numbness, and tingling; problems sleeping; fatigue; and constipation due to pain medication. There was no discussion describing special circumstances that sufficiently supported this request. In the absence of such evidence, the current request for 150g of PC 5001 is not medically necessary.