

<b>Case Number:</b>	CM15-0218112		
<b>Date Assigned:</b>	11/10/2015	<b>Date of Injury:</b>	08/01/1985
<b>Decision Date:</b>	12/24/2015	<b>UR Denial Date:</b>	10/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/05/2015

### 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: 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 57 year old female, who sustained an industrial injury on 8-1-85. The injured worker was diagnosed as having cervicgia, cervical radiculopathy, and fibromyalgia. Treatment to date has included and medication including Relafen, Naprosyn, Lyrica, Zanaflex, and Senokot-S. On 10-14-15 the treating physician noted "she feels that her pain has improved greatly since she has started taking Lyrica. It has reduced from 8 of 10 to 2-3 of 10." On 10-14-15 the treating physician noted no gastrointestinal symptoms on physical exam but noted Linzess was to be started for constipation related to Lyrica use. The injured worker had been taking Lyrica since October 2015. On 10-14-15, the injured worker complained of low back pain and neck pain. The treating physician requested authorization for Lyrica 100mg #60 with 1 refill and Linzess 145mcg #60 with 2 refills. On 10-26-15 the request for Lyrica 100mg #60 with 1 refill was modified to exclude any refills. The request for Linzess 145mcg #60 with 2 refills was modified to exclude any refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**60 Lyrica 100 MG (Pregabalin) with 1 Refill: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

**Decision rationale:** Lyrica (pregabalin) is a medication in the anti-epilepsy class. The MTUS Guidelines and FDA support its use in treating diabetic neuropathy, post-herpetic neuralgia, fibromyalgia, and partial seizures. It can have euphoric and anti-anxiety side effects. When this medication is no longer providing benefit, the Guidelines support weaning over one week to avoid withdrawal effects. The submitted and reviewed documentation indicated the worker was experiencing constipation caused by medication and neck and lower back pain. These records concluded the worker suffered from fibromyalgia and described significantly improved pain and function with the use of pregabalin. In light of this supportive evidence, the current request for 60 tablets of Lyrica (pregabalin) 100mg with one refill is medically necessary.

**60 Linzess 145 MCG with 2 Refills:** 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 54.0. UpToDate, accessed 12/19/2015.

**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 constipation caused by medication and neck and lower back pain. There was no discussion indicating the worker had irritable bowel syndrome with constipation. While these records concluded the worker was suffering from constipation due to pain medication, there was no discussion suggesting a reason a higher dose than is usually required or a large amount of medication was needed. In the absence of such evidence, the current request for 60 tablets of Linzess (linaclotide) 145mcg with two refills is not medically necessary.