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| <b>Case Number:</b>   | CM14-0191034 |                              |            |
| <b>Date Assigned:</b> | 11/24/2014   | <b>Date of Injury:</b>       | 01/17/2006 |
| <b>Decision Date:</b> | 01/09/2015   | <b>UR Denial Date:</b>       | 10/20/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 11/14/2014 |

### 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 Emergency Medicine, and is licensed to practice in New York. 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 patient is a 38-year-old male who was injured on January 17, 2006. The patient continued to experience pain in his back, abdominal bloating, and heartburn. Physical examination was notable for soft, nontender, nondistended abdomen. Diagnoses included status post failed lumbar spine surgery, right-sided L5/S1 radiculopathy, gastroesophageal reflux disease, and irritable bowel syndrome. Treatment included medications, epidural steroid injections, pool therapy, and surgery. Request for authorization for Amitiza drops #60 was submitted for consideration.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Amitiza drops #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA.com

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Opioid-induced constipation treatment

**Decision rationale:** Amitiza is the laxative Lubiprostone. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral

opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. If prescribing opioids has been determined to be appropriate, then ODG recommend that prophylactic treatment of constipation should be initiated. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. Second line options include methyl naltrexone and Lubiprostone. In this case, the patient is diagnosed with irritable bowel syndrome suffering from intermittent diarrhea and constipation. It is also documented that the patient's condition is controlled with Citrucel. Documentation in the medical record does not support the necessity for Amitiza. Therefore, the request is not medically necessary.