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| <b>Case Number:</b>   | CM14-0132860 |                              |            |
| <b>Date Assigned:</b> | 08/22/2014   | <b>Date of Injury:</b>       | 01/01/2007 |
| <b>Decision Date:</b> | 09/24/2014   | <b>UR Denial Date:</b>       | 08/12/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 08/15/2014 |

### 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 Family 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:

This is a 53-year-old female with a 1/1/07 date of injury. The mechanism of injury was a fall at work. According to a progress report dated 7/30/14, the patient complained of left foot pain, low back pain, and right leg pain. Objective findings: limited to vital signs. EMG from 11/29/12 was normal. MRI from 12/3/13 revealed scar tissue over tight nerve root L4-5. Diagnostic impression: low back pain, lumbar spondylosis, left foot pain resolved. Treatment to date: medication management, activity modification. A UR decision dated 8/12/14 denied the request for Amitiza. The pain chapter of ODG states lubiprostone (Amitiza) is recommended only as a possible second-line treatment for opioid-induced constipation. The records do not specify whether the constipation is responding to the patient's use of Colace. The details of constipation symptoms and a gastrointestinal exam were not specified in the records provided.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Amitiza 24 mcg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 12th Edition (web0, 2014, Pain Chapter, Lubiprostone (Amitiza)).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter - Lubiprostone Other Medical Treatment Guideline or Medical Evidence: FDA (Amitiza).

**Decision rationale:** The California MTUS does not address this issue. The ODG states that lubiprostone is recommended only as a possible second-line treatment for opioid-induced constipation. According to the FDA, Amitiza (lubiprostone) is approved to treat Chronic Idiopathic Constipation in adults. Amitiza is also approved to treat constipation caused by opioids in adults with chronic, non-cancer pain. It is noted that the patient is currently taking Colace to prevent opioid-induced constipation from her opioid medication, Norco. However, there is no documentation that Colace is not effective in treating the patient's constipation. In addition, there is no documentation in the reports reviewed that the patient is continuing to complain of constipation. Therefore, the request for Amitiza 24 mcg #120 was not medically necessary.