

Case Number:	CM15-0200845		
Date Assigned:	10/15/2015	Date of Injury:	03/06/2007
Decision Date:	11/25/2015	UR Denial Date:	09/21/2015
Priority:	Standard	Application Received:	10/13/2015

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: California

Certification(s)/Specialty: Family Practice

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 45 year old male, who sustained an industrial-work injury on 3-6-07. A review of the medical records indicates that the injured worker is undergoing treatment for constipation, diarrhea, acid reflux, and abdominal pain. Treatment to date has included pain medication Mapap, Naproxen, Ibuprofen, Tramadol, hydrocodone, Oxaprezin, Meloxicam, Flexeril, Miralax, Levaquin, Methocarbamol, Oxaprozin, Amitiza since at least 7-7-15 Colace since at least 4-28-15, diagnostics, and other modalities. Medical records dated 7-7-15 indicate that the injured worker complains of epigastric pain alleviated with medication. He also complains of generalized abdominal pain not alleviated with medication and he complains of constipation. Per the treating physician report dated 9-14-15 the work status is modified. The physical exam dated 7-7-15 reveals that the abdomen is soft with normoactive bowel sounds. The physician indicates a gastrointestinal consult is pending. He advised the injured worker to follow a low fat, low acid, low cholesterol, low sodium diet. He was instructed to adhere to a course of sleep hygiene. The physician indicates that the urine toxicology dated 6-1-15 was inconsistent with the medications prescribed. The requested services included Amitiza 24mcg-tab, #60 (2x a day) and Colace 250mg, #30 (2x a day). The original Utilization review dated 9-21-15 non-certified the request for Amitiza 24mcg-tab, #60 (2x a day) and Colace 250mg, #30 (2x a day).

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitiza 24mcg/tab, #60 (2x a day): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (updated 9/8/15) 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) Chapter: Pain, Section: Opioid-Induced Constipation Treatment.

Decision rationale: The Official Disability Guidelines comments on the treatment for opioid-induced constipation. 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. 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 don't 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. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for non-cancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. In this case, there is insufficient information to justify the use of a second-line agent such as Amitiza. There is insufficient documentation that the patient has completed an adequate trial of first-line treatments for the constipation. There is insufficient documentation on the medical necessity to continue opioids in this patient. Finally, there is insufficient information on the specific diagnosis regarding the complaint of constipation including an assessment of this condition. For these reasons, Amitiza is not medically necessary at this time.

Colace 250mg, #30 (2x a day): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioid induced constipation.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain, Section: Opioid-Induced Constipation Treatment.

Decision rationale: The Official Disability Guidelines comments on the treatment for opioid-induced constipation. 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. 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 don't 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. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for non-cancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. In this case, there is insufficient information to justify the use of an agent such as Colace. There is insufficient documentation that the patient has completed an adequate trial of first-line treatments for the constipation. There is insufficient documentation on the medical necessity to continue opioids in this patient. Finally, there is insufficient information on the specific diagnosis regarding the complaint of constipation including an assessment of this condition. For these reasons, Colace is not considered as medically necessary at this time.