

<b>Case Number:</b>	CM15-0221549		
<b>Date Assigned:</b>	11/17/2015	<b>Date of Injury:</b>	02/11/2014
<b>Decision Date:</b>	12/24/2015	<b>UR Denial Date:</b>	10/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/11/2015

### 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, Indiana, New York  
Certification(s)/Specialty: Internal 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 48 year old male, who sustained an industrial injury on February 11, 2014. The injured worker was diagnosed as having irritable bowel syndrome and abdominal pain. Treatment to date has included diagnostic studies, surgery, physical therapy, consultations and medication. On March 13, 2015, the injured worker complained of persistent pain in his wrists, neck, low back and left shoulder. He also reported pain in both elbows, knees, ankles and feet. He complained of leg cramps and not sleeping well due to pain symptoms. He was noted to have developed an emotional response to his physical injuries. On September 18, 2015, the injured worker presented for his exam. Objective findings stated "irritable bowel syndrome" and "abdominal pain." The treatment plan included Ketoprofen 20%-Lid 5%-Cycl 1% #60 with three refills, Fenofibrate 145mg #30 with three refills and Lomotil #60 with three refills. On October 21, 2015, utilization review denied a request for Ketoprofen 20%-Lid 5%-Cyclo 1% 60 grams with refills, Fenofibrate 145mg #30 with three refills and Lomotil #60 with three refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20%, Lid 5%, Cyclo% 60 grams with refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Ketoprofen, Lidocaine; topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical analgesics.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, ketoprofen 20%, lidocaine 5%, cyclobenzaprine 1%, 60 g with 3 refills is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Other than Lidoderm, no other commercially approved topical formulation of lidocaine whether cream, lotions or gels are indicated for neuropathic pain. In this case, the injured worker's working diagnoses are irritable bowel syndrome; abdominal pain; severe dyslipidemia; sleep disorder deferred; sexual dysfunction deferred; psychiatric diagnoses deferred and fatty liver. Date of injury is February 11, 2014. Request for authorization is October 6, 2015. According to a March 13, 2015 progress note, subjective complaints include back pain. The injured worker was treated with medications, physical therapy and lumbar epidural steroid injections. Approximately one year prior to the injured worker developed diarrhea with occasional bloody stools. Triglycerides were 1170 and cholesterol was 288. The worker had probable irritable bowel syndrome. A colonoscopy was requested although not authorized. According to the September 18, 2015 progress note, subjectively irritable bowel syndrome is well controlled with fiber. On physical examination, there was an umbilical hernia. There were no other physical findings referencing the abdomen on examination. There are no medications listed. The treatment plan states medications are to be continued plus Imodium for diarrhea. There is a second September 18, 2015 progress note by the requesting provider requesting Lomotil, #60 with three refills as needed for diarrhea. There is no clinical discussion, indication or rationale for a topical analgesic. Ketoprofen is not FDA approved for topical use. Lidocaine and non-Lidoderm form is not recommended. Cyclobenzaprine topical is not recommended. Any compounded product that contains at least one drug (topical ketoprofen, lidocaine and cyclobenzaprine) that is not recommended is not recommended. The treating provider did not specify the number of refills in the request. Consequently, ketoprofen 20%, lidocaine 5%, cyclobenzaprine 1%, 60 g with refills is not recommended. Based on clinical information in the medical record and the peer-reviewed evidence-based guidelines, ketoprofen 20%, lidocaine 5%, cyclobenzaprine 1%, 60 g with 3 refills is not medically necessary.

**Fenofibrate 145mg #30 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Ketoprofen, Lidocaine; topical analgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation  
<https://www.nlm.nih.gov/medlineplus/druginfo/meds/a601052.html>.

**Decision rationale:** Pursuant to Medline plus, Fenofibrate 145 mg, #30 with three refills is not medically necessary. Fenofibrate is used with a low-fat diet, exercise, and sometimes with other medications to reduce the amounts of fatty substances such as cholesterol and triglycerides in the blood and to increase the amount of HDL (high-density lipoprotein; a type of fatty substance that decreases the risk of heart disease) in the blood. Build-up of cholesterol and fats along the walls of the arteries (a process known as atherosclerosis) decreases the blood flow and, therefore, the oxygen supply to the heart, brain, and other parts of the body. This increases the risk of heart disease, angina (chest pain), strokes, and heart attacks. Although fenofibrate decreases the levels of fatty substances in the blood, it has not been shown to decrease the risk of heart attacks or strokes. Fenofibrate is in a class of medications called antilipemic agents. It works by speeding the natural processes that remove cholesterol from the body. In this case, the injured worker's working diagnoses are irritable bowel syndrome; abdominal pain; severe dyslipidemia; sleep disorder deferred; sexual dysfunction deferred; psychiatric diagnoses deferred and fatty liver. Date of injury is February 11, 2014. Request for authorization is October 6, 2015. According to a March 13, 2015 progress note, subjective complaints include back pain. The injured worker was treated with medications, physical therapy and lumbar epidural steroid injections. Approximately one year prior to the injured worker developed diarrhea with occasional bloody stools. Triglycerides were 1170 and cholesterol was 288. The worker had probable irritable bowel syndrome. A colonoscopy was requested although not authorized. According to the September 18, 2015 progress note, subjectively irritable bowel syndrome is well-controlled with fiber. On physical examination there was an umbilical hernia. There were no other physical findings referencing the abdomen on examination. There are no medications listed. The treatment plan states medications are to be continued plus Imodium for diarrhea. There is a second September 18, 2015 progress note by the requesting provider requesting Lomotil, #60 with three refills as needed for diarrhea. The documentation indicates the injured worker has both elevated triglyceride level and elevated cholesterol level. There is no documentation establishing a causal relationship for the elevated triglyceride and cholesterol levels to the industrial injury. As a result, treatment for the elevated cholesterol and triglyceride level is not clinically indicated. Additionally, the type written progress note dated September 18, 2015 does not contain a list of current medications. The start date for Fenofibrate is not specified. Based on the clinical information in the medical record and the peer-reviewed evidence-based guidelines, Fenofibrate 145 mg, #30 with three refills is not medically necessary.

**Lomotil #60 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Ketoprofen, Lidocaine; topical analgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation  
<https://www.nlm.nih.gov/medlineplus/druginfo/meds/a601045.html>.

**Decision rationale:** Pursuant to Medline plus, Lomotil #60 with three refills is not medically necessary. Diphenoxylate is used along with other measures, such as replacement of lost fluids and salts in the body, to treat diarrhea. Diphenoxylate should not be given to children younger than 2 years of age. Diphenoxylate is in a class of medications called anti-diarrheal agents. It works by decreasing activity of the bowel. In this case, the injured worker's working diagnoses are irritable bowel syndrome; abdominal pain; severe dyslipidemia; sleep disorder deferred; sexual dysfunction deferred; psychiatric diagnoses deferred and fatty liver. Date of injury is February 11, 2014. Request for authorization is October 6, 2015. According to a March 13, 2015 progress note, subjective complaints include back pain. The injured worker was treated with medications, physical therapy and lumbar epidural steroid injections. Approximately one year prior to the injured worker developed diarrhea with occasional bloody stools. Triglycerides were 1170 and cholesterol was 288. The worker had probable irritable bowel syndrome. A colonoscopy was requested although not authorized. According to the September 18, 2015 progress note, subjectively irritable bowel syndrome is well controlled with fiber. On physical examination there was an umbilical hernia. There were no other physical findings referencing the abdomen on examination. There are no medications listed. The treatment plan states medications are to be continued plus Imodium for diarrhea. There is a second September 18, 2015 progress note by the requesting provider requesting Lomotil, #60 with three refills as needed for diarrhea. The September 18, 2015 documentation contains different antidiarrheal medications in the treatment plan. The documentation does not contain a start date for Lomotil. The documentation does not contain the start date for Imodium. The documentation is unclear as to which anti-diarrheal the treating provider is requesting. Additionally, the treating provider is requesting Lomotil to be taken on an as needed basis with three refills. This appears to be an excessive number of Lomotil tablets to be taken on an as needed basis without documentation of objective functional improvements. Based on the clinical information in the medical record, peer-reviewed evidence-based guidelines and conflicting documentation as to which anti-diarrheal medication the treating provider is requesting, Lomotil #60 with three refills is not medically necessary.