

<b>Case Number:</b>	CM14-0061982		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	10/28/2005
<b>Decision Date:</b>	09/30/2014	<b>UR Denial Date:</b>	04/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/02/2014

### 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 Occupational 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:

The patient is a 44 year-old male with date of injury May 01, 2004. The medical document associated with the request for authorization, a primary treating physician's progress report, dated March 18, 2014, lists subjective complaints as improving abdominal pain, constipation, and gastrointestinal reflux disease. Objective findings: the primary treating physician's progress report (PR-2) attached to the request for authorization did not include any objective examination or information about the patient's symptomology. Diagnosis: 1. Abdominal pain 2. Constipation 3. Gastrointestinal reflux disease 4. Gastritis 5. Sleep disorder. The medical records supplied for review document that the patient had not been prescribed any of the following medications prior to the request for authorization on March 18, 2014, with the exception of Amitiza, which had been prescribed by the primary treating physician three months previously. Medications Included: 1. Gaviscon, one bottle, SIG: one tablespoon thrice daily; 2. Citrucel, #180 SIG: one to two tablets thrice daily; 3. Miralax, one bottle, 17grams SIG: with water as needed daily; 4. Probiotics, #90 SIG: twice daily; 5. Amitiza 24mcg, #60 SIG: one tablet twice daily (been taking at least three months); 6. Dexilant 60mg, #30 SIG: daily; 7. Sentra PM, #60 SIG: at bedtime; and 8. Restoril 15mg, #45 SIG: four times a day.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**GI Profile:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 3.

**Decision rationale:** For all conditions or injuries not addressed in the California MTUS Guidelines, the authorized treatment and diagnostic services in the initial management and subsequent treatment for presenting complaints shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community pursuant to section 9792.25(b). The request for a GI profile is nonspecific and a poorly defined. Therefore, the request is not medically necessary.

**Gaviscon (1-bottle):** Overturned

**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 Gaviscon U.S. home page. GlaxoSmithKline.

**Decision rationale:** Gaviscon is a non-prescription medicine, which is taken by mouth to treat heartburn and gastroesophageal reflux disease (GERD). The California MTUS Guidelines and the Official Disability Guidelines are silent on Gaviscon. The manufacturer's website was referenced. The Gaviscon is a safe and fairly effective method of treating gastroesophageal reflux disease. The patient has an industrially related diagnosis GERD that is improving with medication. Therefore, the request is medically necessary.

**Citrucel (#180):** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

**Decision rationale:** Citrucel is derived from methyl cellulose in this used to treat constipation by producing a softer and bulky stool. The patient suffers from opioid-induced constipation. The Chronic Pain Medical Treatment Guidelines makes provision for the prophylactic treatment of constipation secondary to chronic opiate use. Therefore, the request is medically necessary.

**Miralax (1-bottle, 17gm with 8oz of water):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 77.

**Decision rationale:** Although The Chronic Pain Medical Treatment Guidelines makes provision for the prophylactic treatment of constipation secondary to chronic opiate use, the patient is being prescribed and other laxative. In addition, MiraLax is intended for short-term use only. Therefore, the request is not medically necessary.

**Probiotics (#90):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Medical Foods.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical food.

**Decision rationale:** Probiotics are microorganisms that provide health benefits when consumed, as claimed by some. The term probiotic is currently used to name ingested microorganisms associated with beneficial effects to humans and animals. Probiotics are currently considered a medical food. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Therefore, the request is not medically necessary.

**Amitiza (24mcg, #60):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 77.

**Decision rationale:** Amitiza (lubiprostone) is approved by the FDA for the treatment of chronic constipation of unknown cause in adults, as well as irritable bowel syndrome associated with constipation in women. The patient does not suffer from idiopathic constipation. The cause of the patient's constipation is known to be opioid-induced. Therefore, the request is not medically necessary.

**Dexilant (60mg, #30):** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** Dexlansoprazole is a proton pump inhibitor. According to the Chronic Pain Medical Treatment Guidelines, prior to starting the patient on a proton pump inhibitor, physicians are asked to evaluate the patient and to determine if the patient is at risk for gastrointestinal events. Criteria used are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID. There is no documentation that the patient has any of the risk factors needed to recommend the proton pump inhibitor Dexilant. The patient suffers from gastroesophageal reflux disease, but there is no documentation that he has a history of peptic ulcer disease or GI bleeding. Therefore, the request is medically necessary.

**Sentra PM (#60, 3 bottles): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - Medical Foods.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical food.

**Decision rationale:** Sentra is a medical food. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Therefore, the request is not medically necessary.

**Restoril (15mg, #45): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Antidepressants.

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

**Decision rationale:** The Official Disability Guidelines do not recommended benzodiazepines such as Restoril for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks.

The patient has been taking Restoril for at least 4 months. Therefore, the request is not medically necessary.