

<b>Case Number:</b>	CM14-0214854		
<b>Date Assigned:</b>	01/07/2015	<b>Date of Injury:</b>	03/23/2003
<b>Decision Date:</b>	02/28/2015	<b>UR Denial Date:</b>	11/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/22/2014

### 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. 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 (IW) is a 60-year-old man with a date of injury of March 23, 2003. The mechanism of injury was not documented in the medical record. The injured worker's working diagnoses are gastrointestinal reflux disease (GERD) secondary to NSAIDs; gastropathy, secondary to NSAIDs; constipation, secondary to Vicodin; chest pain; sleep disorder, rule out obstructive sleep apnea; history of coronary artery disease, status post stent X 2; neurogenic bladder and fecal and urinary incontinence as per urologist; hypersensitive/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy, non-industrial. Pursuant to the Secondary Treating Physician's Progress Report (internal Medicine) dated October 14, 2014, the IW presents for a follow-up. He has seen the GI specialist and the urologist as recommended. The IW reports a decreased number of daily incontinence episodes from six to two, but it still continues. He notes improving acid reflux (but not well controlled with Protonix). There is no change in constipation. He notes chest pain and shortness of breath upon exertion. He complains of forgetfulness. There are no significant findings present on physical examination. There was no past medical history documented. The IW was given Gaviscon, one bottle and Colace 100mg #90. The treating physician prescribed the following medications: Probiotic, Protonix, Levitra, GABAdone/Ranitidine, Sentra AM, and Sentra PM. The provider did not provide a clinical rationale for prescribing the aforementioned medications. The IW is receiving blood pressure medications from his private physician. The current request is for Probiotic #60, Protonix 40mg #30, Levitra 20mg #30, GABAdone #60, Ranitidine 150mg #30, Sentra AM #60, and Sentra PM #60.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Probiotic qty:60.00:** Upheld

**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 Other Medical Treatment Guideline or Medical Evidence: <http://www.uptodate.com/contents/probiotics-for-gastrointestinal-diseases>.

**Decision rationale:** Pursuant to Up-To-Date, probiotics are not medically necessary. Probiotics are microorganisms that have beneficial properties for the host. See the attached link for details. In this case, the injured worker's working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic bladder and fecal and urinary incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems or causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. However, there are no clinical indications or clinical rationales in the medical record to support the use of probiotic. Consequently, absent clinical documentation to support the ongoing use of probiotics, probiotics are not medically necessary.

**Protonix 40mg qty:30.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Omeprazole Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Section, NSAI and GI Effects.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, Protonix 40mg #30 is not medically necessary. Protonix is a proton inhibitor. Proton pump inhibitors are indicated in certain patients taking nonsteroidal anti-inflammatory drugs that are at risk for certain gastrointestinal events. These risks include, but are not limited to, age greater than 65; history testicles for G.I. bleeding; concurrent use of aspirin or corticosteroids; or high-dose multiple nonsteroidal anti-inflammatory drugs. In this case, the injured worker's working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic

bladder and fecal and urinary incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems or causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. The documentation contains a diagnosis of gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs. The subject of section indicates the injured worker has acid reflex that is not well controlled with Protonix. There is no past medical history and the documentation indicating gastroesophageal reflux disease. There is no clinical indication or clinical rationale in the medical record to support the use of Protonix. Consequently, absent clinical documentation to support the ongoing use of Protonix, Protonix are not medically necessary.

**Levitra 20mg qty:30.00:** Upheld

**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 Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/levitra.html>.

**Decision rationale:** Pursuant to [REDACTED], Levitra is not medically necessary. Levitra is used to treat erectile dysfunction. For additional details see the attached link. In this case, the injured worker's working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic bladder and fecal and urinary incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems or causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. However, there are no clinical indications or clinical rationales in the medical record to support the use of Levitra. The diagnosis does not indicate any difficulties with erectile dysfunction or hypogonadism secondary to prolonged use of opiates. Consequently, absent clinical documentation to support Levitra, Levitra is not medically necessary.

**Gabadone qty:60.00:** 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 (Chronic), Medical food

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

**Decision rationale:** Pursuant to the Official Disability Guidelines, GABAdone #60 is not medically necessary. Medical foods are not recommended for chronic pain. Medical foods are not recommended and have not been shown to produce meaningful benefits or improvements in functional outcomes. GABAdone is a medical food. In this case, the injured worker's working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic bladder and fecal and urinary incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems or causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. However, there are no clinical indications or clinical rationales in the medical record to support the use of GABAdone. The guidelines do not recommend medical foods. GABAdone is a medical food. Consequently, GABAdone is not recommended and not medically necessary.

**Ranitidine 150mg qty:30.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Section, NSAI and GI Effects. Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/ranitidine.html>.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, ranitidine 150 mg #30 is not medically necessary. Ranitidine is an H2 receptor blocker. It works by reducing the amount of acid in the stomach. It is used to treat and prevent ulcers in the stomach and intestines and conditions that produce too much acid such as Zollinger-Ellison syndrome. See guidelines for additional details. In this case, the injured worker's working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic bladder and fecal and urinary incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems or causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. The documentation contains a diagnosis of gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs. The subject of section indicates the injured worker has acid reflex that is not well controlled with Protonix. There is no past medical history and the documentation indicating gastroesophageal reflux disease. There is no clinical indication or clinical rationale in the medical record to support the dual use of ranitidine with Protonix. Additionally, the documentation is unclear as to whether the gastroesophageal reflux is a pre-existing medical

problem not related to the industrial injury. Consequently, absent clinical documentation to support the ongoing use of Ranitidine, Ranitidine is not medically necessary.

**Sentra AM qty:60.00:** Upheld

**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 Official Disability Guidelines (ODG); Pain Section, Medical foods.

**Decision rationale:** Pursuant to the Official Disability Guidelines, Sentra AM is not medically necessary. Medical foods are not recommended for chronic pain. Medical foods are not recommended and have not been shown to produce meaningful benefits or improvements in functional outcomes. Sentra AM is a medical food. In this case, the injured workers working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic bladder and fecal and urinary incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems or causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. However, there are no clinical indications or clinical rationales in the medical record to support the use of Sentra AM. The guidelines do not recommend medical foods. Sentra AM is a medical food. Consequently, Sentra AM is not recommended and not medically necessary.

**Sentra PM qty:60.00:** 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 (Chronic), Sentra PM

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

**Decision rationale:** Pursuant to the Official Disability Guidelines, Sentra PM is not medically necessary. Medical foods are not recommended for chronic pain. Medical foods are not recommended and have not been shown to produce meaningful benefits or improvements in functional outcomes. Sentra PM is a medical food. In this case, the injured worker's working diagnoses according to the internal medicine consultation are gastroesophageal reflux disease, secondary to nonsteroidal anti-inflammatory drugs; guess property, secondary to nonsteroidal anti-inflammatory drugs; constipation, secondary to Vicodin; chest pain; sleep disorder; history coronary artery disease, status post stent times to; neurogenic bladder and fecal and urinary

incontinence; hypertension/arteriosclerotic retinopathy; and hypertension with left ventricular hypertrophy. The documentation is unclear as to how these medical problems are causally related to the work injury. The documentation does not contain a past medical history. The progress note dated October 14, 2014 lists all the medications requested. However, there are no clinical indications or clinical rationales in the medical record to support the use of Sentra PM. The guidelines do not recommend medical foods. Sentra PM is a medical food. Consequently, Sentra PM is not recommended and not medically necessary.