

<b>Case Number:</b>	CM15-0092666		
<b>Date Assigned:</b>	05/21/2015	<b>Date of Injury:</b>	08/06/2008
<b>Decision Date:</b>	07/14/2015	<b>UR Denial Date:</b>	05/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/13/2015

### 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 53 year old male, who sustained an industrial injury on 8/6/2008. The current diagnoses are gastroesophageal reflux disease (improved), secondary to NSAIDs, irritable bowel syndrome, hemorrhoids, secondary to irritable bowel syndrome, and rectal bleeding, secondary to hemorrhoids (currently asymptomatic). According to the progress report dated 2/11/2015, the injured worker notes unchanged constipation, diarrhea, and hemorrhoids. He denies bright red blood per rectum. He reports improved acid reflux. The physical examination of the abdomen reveals tenderness to palpation over the epigastric region. No distention noted. The current medications are Dexilant, Ranitidine, Gaviscon, Citrucel, Simethicone, Probiotics, and Bentyl. Treatment to date has included medication management, abdominal ultrasound, and 2D echocardiogram. The plan of care includes prescription for Trepadone, Sentra AM, Gaviscon, Carafate liquid, and Simethicone.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Trepadone #90 4 bottles:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation literature from the drug manufacturer.

**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), Trepadone and Medical Food.

**Decision rationale:** MTUS is silent concerning Trepadone. ODG states that a medical food is "a food which is formulated to be consumed or administered internally 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." ODG comments on Trepadone directly, "Trepadone is a medical food from [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)." ODG states, "Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia." Medical records do not indicate that this medication would be used to treat epilepsy, spasticity and tardive dyskinesia. ODG states, "L- Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." This component is not indicated. ODG states, "L-Arginine: This supplement is not indicated in current references for pain or inflammation." It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome. Medical records do not indicate that this medication would be utilized for urine detoxification or for treatment off the other indicated reasons. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there are several components of this medication that are not recommended per guidelines. As such, the request for TREPIDONE is not medically necessary.

**Sentra AM #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 (ODG), pain chapter, drug manufacturer information.

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

**Decision rationale:** Sentra AM is a medical food that contains choline and acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. In addition ODG states that a medical food is Definition: 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 eternally 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. To be considered the product must, at a

minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision." ODG specifically states "Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency." Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra AM #60 is not medically necessary.

**Gaviscon #1 bottle 2 refills:** 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 NSAIDs; GI distress Page(s): 68-69. Decision based on Non-MTUS Citation WebMD: <http://www.webmd.com/drugs/2/drug-18801-2123/gaviscon-oral/calciumcarbonateantacid-oral/details> Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk Other Medical Treatment Guideline or Medical Evidence: Uptodate.com, NSAIDs (including aspirin): Primary prevention of gastroduodenal toxicity.

**Decision rationale:** MTUS is silent on Gaviscon. The above cited reference states the following: "Gaviscon is a non-prescription medicine, which is taken orally to treat heartburn and gastroesophageal reflux disease (GERD). [1] Gaviscon is available as a solid, syrup or tablet. It is produced and distributed in the UK, Ireland, Australia, India and Malaysia by [REDACTED], [2] in the US by [REDACTED] and in Canada by [REDACTED]. [3] The formulation of Gaviscon varies by manufacturer. The three active ingredients in [REDACTED] version are sodium alginate, a bicarbonate (either sodium or potassium in variants) and an antacid (calcium carbonate). [4], [5] The [REDACTED] variant lists only antacids as its active ingredients (aluminum hydroxide and either magnesium carbonate or magnesium trisilicate). Alginic acid and sodium bicarbonate are listed as inactive ingredients. [6], [7] This medication is used to treat symptoms caused by too much stomach acid such as heartburn, upset stomach, or indigestion. It is an antacid that works by lowering the amount of acid in the stomach." Here is currently taking Ranitidine which is an H2 antagonist used for the treatment of stomach ulcers and gastroesophageal reflux. MTUS states, "Determine if the patient is at risk for gastrointestinal events: (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 (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily); or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." Uptodate states regarding H2 antagonist for GI prophylaxis, "Standard doses of H2 receptor antagonists were not effective for

the prevention of NSAID-induced gastric ulcers in most reports, although they may prevent duodenal ulcers [33]. Studies that detected a benefit on gastric ulcer prevention were short-term (12 to 24 weeks) and focused on endoscopic rather than clinical endpoints." Medical notes say his reflux is improving, and it is not clear how Gaviscon has any further benefit compared to the Ranitidine alone which the employee is currently on. Therefore, the request is not medically necessary.

**Carafate Liquid #120 2 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation WebMD.com.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.medicinenet.com/sucralfate/article.htm>.

**Decision rationale:** MTUS is silent on Carafate (Sucralfate). The above cited resource says the following: "Sucralfate is a unique oral drug that is used for treating ulcers of the upper gastrointestinal tract. Chemically, it is a complex of the disaccharide sugar, sucrose, combined with sulfate and aluminum. It is minimally absorbed into the body, and its actions are entirely on the lining of the stomach and duodenum. Although its mechanism of action is not entirely understood, the following actions are thought to be important for its beneficial effects: sucralfate binds to the surface of ulcers (attaching to exposed proteins) and coats the ulcer, thus protecting the ulcer surface to some extent from further injury by acid and pepsin; sucralfate directly inhibits pepsin (an enzyme that breaks apart proteins) in the presence of stomach acid; sucralfate binds bile salts coming from the liver via the bile thus protecting the stomach lining from injury caused by the bile acids; sucralfate may increase prostaglandin production, and prostaglandins are known to protect the lining of the stomach. Sucralfate was approved by the FDA in 1981. PRESCRIBED FOR: Sucralfate is used for the treatment of peptic ulcer disease and to prevent recurrent ulcers after healing of the ulcer has been achieved. It also has been used to relieve or prevent ulcers caused by nonsteroidal anti-inflammatory drugs (NSAIDs) but is less effective than misoprostol (Cytotec). Sucralfate also is used in the treatment of patients with gastroesophageal reflux disease (GERD). The employee does not meet the criteria for peptic ulcer disease, and so the request is not medically necessary.

**Simethicone 80 mg #60 2 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medline Plus website.

**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: UpToDate, Simethicone.

**Decision rationale:** MTUS and ACOEM are silent specifically in regards to Gaviscon (simethicone), therefore other guidelines were utilized. Simethicone is an over the counter medication used to treat flatulence, bloating, pressure, and discomfort of gas. The above cited reference states, Simethicone, which causes gas bubbles to break and coalesce, is widely used for

treating gaseous complaints. However, it has not been shown to be of benefit. Additionally, the reference recommends, "Dietary measures including the avoidance of foods that may contribute to the problem is an obvious initial step" and further suggests "Limiting dietary ingestion of known gas-producing foods such as cabbage, onions, broccoli, brussel sprouts, wheat, and potatoes should be recommended as a therapeutic trial." The medical records do not document the first line treatment (dietary avoidance of trigger foods) and the results of the trial. As such, the request for Gaviscon is not medically necessary.