

<b>Case Number:</b>	CM15-0079239		
<b>Date Assigned:</b>	06/01/2015	<b>Date of Injury:</b>	07/05/2002
<b>Decision Date:</b>	07/07/2015	<b>UR Denial Date:</b>	03/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/24/2015

### 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: Florida

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 (IW) is a 43-year-old female who sustained an industrial injury on 07/05/2002. Diagnoses include gastroesophageal reflux disease, mild chronic gastritis, irritable bowel syndrome and internal hemorrhoids-small. Treatment to date has included medications; dietary, medication and weight loss recommendations; esophagogastroduodenoscopy (EGD); colonoscopy; labs. According to the secondary treating physician's progress notes dated 2/24/15, the IW reported improved acid reflux and epigastric pain; headaches, shortness of breath, constipation and bright red blood from the rectum was unchanged. On examination, lungs were clear and 1+ abdominal tenderness was present on palpation. A request was made for Gaviscon, 1 bottle with 2 refills; Simethicone 80mg, #60 with 2 refills; Gabadone #60, 3 bottles, Sentra AM #60, 3 bottles and one urine toxicology screen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gaviscon - 1 bottle with 2 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69 of 127.

**Decision rationale:** In accordance with California MTUS guidelines, PPIs (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDs and if the patient has gastrointestinal risk factors. Whether the patient has cardiovascular risk factors that would contraindicate certain NSAID use should also be considered. This patient has GERD and is taking Prilosec, a PPI. Gaviscon is another medication that is utilized for reflux symptoms. Likewise, as this patient is already on a GERD medication, this additional GERD medication is not medically necessary, as no compelling documentation has been provided that explains why two reflux medications are necessary.

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

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation MedGenMed. 2005; 7(1): 18. Published online 2005 Jan 10. PMCID: PMC1681432. Expert Commentary - Bloating, Distension, and the Irritable Bowel Syndrome. Richard Lea, MD, Clinical Research Fellow and Peter J. Whorwell, MD, Professor of Medicine and Gastroenterology.

**Decision rationale:** MTUS, ACOEM, and ODG guidelines do not address the prescription of Simethicone. Therefore, outside sources were referenced. According to a PubMed article entitled, Expert Commentary - Bloating, Distension, and the Irritable Bowel Syndrome, "A number of medications aimed at limiting intestinal gas volumes have been suggested for use in patients with bloating, although experience with these agents has largely been disappointing. Simethicone, an antisurfactant is frequently used by patients, but there appears to be little objective evidence of benefit over placebo." This patient has been taking Simethicone for Irritable bowel syndrome symptoms. Likewise, this request is not medically necessary.

**Gabadone #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, Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Nutrient Pharmacology <http://nutrientpharmacology.com/gabadone.html>.

**Decision rationale:** MTUS, ACOEM, and ODG guidelines do not address this request, and likewise outside sources were referenced. Gabadone is a "medical food" that is not FDA approved. It contains the amino acids that are the precursors to the neurotransmitters that induce sleep. Sources state that some individuals who have problems with insomnia lack these amino acids. As no testing has been performed to determine if this patient is truly low on these

particular amino acids, and as this medication is not FDA approved, the request 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, Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Nutrient Pharmacology Sentra AM [http://nutrientpharmacology.com/sentra\\_AM.html](http://nutrientpharmacology.com/sentra_AM.html).

**Decision rationale:** Sentra AM is a "medical food." It is not FDA approved. MTUS, ACOEM, and ODG guidelines do not address this request, and likewise outside sources were referenced. Outside sources state that this drug is designed to increase and maintain the production of acetylcholine by peripheral neurons and brain cells. Its purpose is to help manage fatigue and deficiencies associated with memory and concentration. As this patient has not been tested and found to specifically have any deficiencies, and since this drug is not FDA approved, the request is not medically necessary.

**1 Urine toxicology screen:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, steps to avoid misuse/addiction.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for the use of opioids Page(s): 77-79.

**Decision rationale:** The MTUS guidelines recommend frequent and random urine drug screens where aberrant behavior is suspected. There is no documentation provided that this patient is taking an addictive substance that would require a drug screen. Therefore, this request for drug testing is not medically necessary.