

Case Number:	CM15-0098255		
Date Assigned:	05/29/2015	Date of Injury:	01/06/2002
Decision Date:	07/17/2015	UR Denial Date:	05/10/2015
Priority:	Standard	Application Received:	05/21/2015

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: Pennsylvania

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 50 year old female who sustained an industrial injury on January 6, 2002. The diagnoses include low back pain, abdominal pain, acid reflux, status post H. pylori treatment, sleep disorder rule out obstructive sleep apnea, and weight gain. Additional diagnoses include diabetes and hypertension. Treatment to date has included H. pylori treatment, medications, physical therapy, and lumbar fusion. An upper gastrointestinal (GI) series on 7/17/14 was reported as unremarkable. Ultrasound of the abdomen on 10/15/14 showed normal gall bladder and no sonographic evidence of choecystitis. In January, February, and March 2015, the injured worker reported worsening sleep quality due to back and leg pain, improving gastroesophageal reflux, and minimal lower abdominal pain. Examination showed a soft abdomen with normoactive bowel sounds. Currently, in April 2015, the injured worker reports improved gastroesophageal reflux disease and minimal lower abdominal pain. She reports unchanged constipation. On physical examination, the injured worker's abdomen was soft with normoactive bowel sounds. A barium enema was noted to be pending. Low fat, low acid, low cholesterol, low sodium and low glycemic diet was recommended. The treatment plan includes barium enema with medical supplies to include Colace, benty, gabadone, sentra AM and theramine. On 5/11/15, Utilization Review non-certified requests for the items currently under Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Barium enema: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Radiology, Gastrointestinal Imaging, Fluoroscopy, Barium Enema.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Gastroenterological Association medical position statement on constipation. Gastroenterology 2013 Jan; 144(1): 211-7. Qaseem A et al. Screening for colorectal cancer: a guideline statement from the American College of physicians. Ann Intern Med 2012 Mar 6; 156(5): 378-86.

Decision rationale: Per the American Gastroenterological Association medical position statement on constipation, clinical evaluation of constipation should include discontinuation of medications that can cause constipation before further testing. A careful digital rectal examination should be performed. A colonoscopy should not be performed in patients without alarm features (such as blood in the stools, anemia, and weight loss) unless age-appropriate colon cancer screening has not been performed. Barium enema may be considered as a screening method for detection of colon cancer, although colonoscopy is generally regarded as the gold standard. The treating physician has not discussed the reason for the request for a barium enema. In this case, the injured worker was noted to have abdominal pain, acid reflux, and constipation. Prior testing included an upper GI series and ultrasound of the abdomen, which were unremarkable. Recent abdominal examination was also unremarkable. There was no documentation of rectal examination or discussion of medications, which may be causing constipation or abdominal pain. Dietary recommendations documented did not include recommendations for dietary changes for the treatment of constipation. There was no documentation of alarm features such as blood in the stools, anemia, or weight loss. There was no discussion of any prior colonoscopy. Due to lack of specific indication, the request for barium enema is not medically necessary.

Colace 100mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Management of constipation, Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids: Initiating Therapy [with opioids] Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: opioid induced constipation treatment.

Decision rationale: The MTUS notes that when initiating therapy with opioids, prophylactic treatment of constipation should be initiated. Per the ODG, constipation occurs commonly in patients receiving opioids. If prescribing opioids has been determined to be appropriate,

prophylactic treatment of constipation should be initiated. First line treatment includes increasing physical activity, maintaining appropriate hydration, and diet rich in fiber. Some laxatives may help to stimulate gastric motility, and other medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Although laxatives are indicated when opioids are prescribed, the documentation does not indicate current use of opioid medications. The injured worker was noted to have constipation, but there was no discussion of use of first line treatment of constipation as described above. A rectal examination was not documented. Due to lack a complete physical examination in light of symptom of constipation, and lack of use of first line treatments for constipation, the request for colace is not medically necessary.

Bentyl 20mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Management of constipation, Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core, American Geriatrics Society.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: Treatment of irritable bowel syndrome. In UpToDate, edited by Ted W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Bentyl is an anticholinergic antispasmodic medication indicated for treatment of functional bowel/irritable bowel syndrome. Pharmacologic treatment of irritable bowel syndrome is indicated in patients with mild to moderate symptoms who fail to respond to lifestyle and dietary modification and for patients with moderate to severe symptoms of irritable bowel syndrome that affect quality of life. Antispasmodics provide short-term relief in symptoms of abdominal pain associated with irritable bowel syndrome, but their long-term efficacy has not been established. In this case, there was no documentation of irritable bowel syndrome. The treating physician has not discussed the reason for prescription of bentyl. Due to lack of specific indication, the request for bentyl is not medically necessary.

Gabadone #60 1 bottle: 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, Gabadone.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: Gabadone, insomnia treatment, medical food.

Decision rationale: Gabadone is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. The ODG states that medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The ODG specifies that

pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The treating physician documented that the injured worker had sleep disturbance due to back and leg pain, without further discussion or evaluation. A diagnosis of sleep disorder rule out sleep apnea was noted, but no testing for sleep apnea was submitted or discussed. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Gabadone is not recommended for sleep disorders based on limited available research. Due to ODG recommendation against use of medical foods and against use of Gabadone, and lack of sufficient evaluation for sleep disturbance, the request for Gabadone is not medically necessary.

Sentra AM #60 1 bottle: 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, 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) chronic pain chapter: Medical food.

Decision rationale: Sentra AM is a medical food intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. The FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There is no documentation of a specific nutritional deficiency, which would be expected to be improved with this medical food. The ODG states that medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. As such, the request for sentra AM is not medically necessary.

Theramine #60 1 bottle: 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, Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: medical food, theramine.

Decision rationale: Theramine is medical food intended for use in the management of chronic pain syndromes which contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine,

histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). Per the ODG, theramine is not recommended for the treatment of chronic pain. The FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There is no documentation of a specific nutritional deficiency, which would be expected to be improved with this medical food. As such, the request for theramine is not medically necessary.