

Case Number:	CM15-0200183		
Date Assigned:	10/20/2015	Date of Injury:	10/28/2006
Decision Date:	12/01/2015	UR Denial Date:	09/30/2015
Priority:	Standard	Application Received:	10/12/2015

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: Tennessee, Florida, Ohio
 Certification(s)/Specialty: Surgery, Surgical Critical Care

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 53 year old male who sustained a work-related injury on 10-28-06. Medical record documentation on 4-16-16 revealed the injured worker was being treated for gastritis, gastroesophageal reflux disease, irritable bowel syndrome, obstructive sleep apnea, status post H. pylori treatment and internal hemorrhoids (4-16-15, 7-14-15). The injured worker reported abdominal pain and unchanged headaches. He noted improvement in gastroesophageal reflux disease and constipation. He had unchanged sleep quality and dizziness. The injured worker reported chest pain and shortness of breath (4-16-15 and 7-14-15). Objective findings for 4-16-15 and 7-14-15 included a regular heart rate and rhythm with no rubs, gallops or murmurs. He had a soft abdomen with 1+ diffuse abdominal tenderness. He had no hepatosplenomegaly or guarding and no rebound tenderness. The treatment plan included laboratory evaluation, Sudo-scan, electrocardiogram, 2D Echocardiogram with Doppler, carotid ultrasound, Dexilant 60 mg, Gaviscon three times per day, Citrucel 1-2 tablet 3 times per day, Miralax 17g, Sentra AM, Sentra PM and urine toxicology. On 9-30-15, the Utilization Review physician determined Sentra PM #60 (3 bottles), Sentra AM #60 (3 bottles), Miralax 1 bottle, Citrucel #120, Gaviscon 1 bottle, Dexilant 60 mg #30, GI Profile (TSH, AML, CMPR, CBC) and urine toxicology screen were not medically necessary and modified the request for electrocardiogram, 2D echocardiogram with Doppler and carotid ultrasound to electrocardiogram only.

IMR ISSUES, DECISIONS AND RATIONALES

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

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 (ODG), Pain Procedure Summary Online Version.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Nutrition, and Sentra AM/PM.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The Official Disability Guidelines state that Sentra PM is not recommended. Sentra PM is a medical food from Targeted Medical Pharm, Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. There was no rationale submitted in the submitted documentation to indicate the use of Sentra PM other than the patient's chronic pain syndrome. There were no other significant factors provided to justify the use outside of the current guidelines. Given the evidence based guidelines and the lack of submitted documentation, the request would not be indicated. Therefore, based on the submitted medical documentation, the request for Sentra PM 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 Procedure Summary Online Version.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Nutrition, and Sentra AM/PM.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The Official Disability Guidelines state that Sentra AM is not recommended. Sentra AM is a medical food from Targeted Medical Pharm, Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. There was no rationale submitted in the submitted documentation to indicate the use of Sentra AM other than the patient's chronic pain syndrome. There were no other significant factors provided to justify the use outside of the current guidelines. Given the evidence based guidelines and the lack of submitted documentation, the request would not be indicated. Therefore, based on the submitted medical documentation, the request for Sentra AM is not medically necessary.

Miralax (1 bottle): Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary Online Version.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Medications for chronic pain, Opioids for chronic pain.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of this request for this patient. Per the California MTUS guidelines, use of a laxative is recommended to prevent opioid induced constipation. MiraLax is a medication use to deal with constipation. MiraLax medication is used for prophylactic treatment of opioid induced constipation and is supported by guidelines for patients with chronic opioid use. This patient meets established guidelines for the use of MiraLax medication since the clinical records submitted do support the fact that this patient has chronic constipation with the need for laxative therapy due to large internal hemorrhoids. Therefore, based on the submitted medical documentation, the request for MiraLax is medically necessary.

Citrucel #120: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary Online Version.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Management of Constipation in Older Adults. Mounsey A, Raleigh M, Wilson A. Am Fam Physician. 2015 Sep 15; 92(6): 500-4.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address the topic of this medication. Therefore, outside sources were sought. Citrucel is methylcellulose. It is approved for short term relief of constipation but acting as a bulking laxative. The clinical records submitted do support the fact that this patient has chronic constipation with the need for laxative therapy due to large internal hemorrhoids. Therefore, based on the submitted medical documentation, the request for Citrucel is medically necessary.

Gaviscon (1 bottle): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Prescribing Guidelines and Indications for

Gavisconhttp://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=018685&TABLE1=OB_OTC.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address the topic of antacid medications. Therefore, outside sources were sought. Per the FDA prescribing guidelines, antacids are used for the short term treatment of heartburn and flatulence. Use of an antacid is not supported with this patient's NSAID and opiate therapies. Therefore, based on the submitted medical documentation, the request for Gaviscon is not medically necessary.

Dexilant 60mg #30: 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 Procedure Summary Online Version.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of the requested prescription for this patient. The clinical records submitted do not support the fact that this patient has refractory GERD resistant to H2 blocker therapy or an active h. pylori infection. The California MTUS guidelines address the topic of proton pump prescription. In accordance with California MTUS guidelines, PPI's (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDS and if the patient has gastrointestinal risk factors. This patient is not on NSAIDS. Additionally, per the Federal Drug Administration's (FDA) prescribing guidelines for PPI use, chronic use of a proton pump inhibitor is not recommended due to the risk of developing atrophic gastritis. Short-term GERD symptoms may be controlled effectively with an H2 blocker unless a specific indication for a proton pump inhibitor exists. This patient's medical records support that he has GERD and a history of H. Pylori (status post treatment). However, the patient has no documentation of why chronic PPI therapy is necessary using a third generation PPI. His GERD is not documented to be refractory to 1st or second generation PPI therapy and he has no records that indicate an active h. pylori infection. Therefore, based on the submitted medical documentation, the request for Dexilant prescription is not medically necessary.

GI Profile (TSH, AML, CMPR, CBC): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goldman: Cecil Medicine, 23rd ed. Chapter 134-Approach to the Patient with Gastrointestinal Disease.

MAXIMUS guideline: Decision based on MTUS Stress-Related Conditions 2004, Section(s): Diagnostic Testing.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of CBC, SMA 19 and ESR testing with venipuncture for this patient. The California MTUS guidelines state that: "An erythrocyte sedimentation rate (ESR), complete blood count (CBC), and tests for autoimmune diseases (such as rheumatoid factor) can be useful to screen for inflammatory or autoimmune sources of joint pain. All of these tests can be used to confirm clinical impressions, rather than purely as screening tests in a "shotgun" attempt to clarify reasons for unexplained shoulder complaints."The medical documentation submitted does not clearly indicate that this patient exhibits signs or symptoms of a rheumatologic or idiopathic inflammatory condition. Evidence of anemia (macrocytic or otherwise) is not demonstrated on physical exam to indicate a CBC. Furthermore, the patient is documented to have no concern for acute electrolyte abnormalities or abnormal liver function, which would indicate the necessity for a CMPR test. Screening for AML and TSH are not indicated without clear evidence of disease or signs/symptoms of dysfunction. Therefore, based on the submitted medical documentation, the request for a GI profile is not medically necessary.

Urine toxicology screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary Online Version.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a urine drug screen for this patient. The clinical records submitted do not support the fact that this patient has been documented to have a positive drug screen for illicit or non-prescribed substances. The MTUS guidelines recommend frequent and random urine drug screens where aberrant behavior is suspected. This patient has not been documented to have suspicion of aberrant behavior. His pain is documented as well controlled. Therefore, based on the submitted medical documentation, the request for drug screening is not medically necessary.

2D echo with doppler: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zipes: Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 7th ed., p. 261.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Antman EM, Smith SC, Alpert JS, et al. ACC/AHA/ASE 2003 Guideline Update for the Clinical Application of Echocardiography. ACC/AHA Practice Guidelines. Dallas, TX: American Heart Association; 2003. Available at: <http://www.americanheart.org/> Gottdiener JS, Bednarz J, Devereix R, et al. American Society of Echocardiography recommendations for use of echocardiography in clinical trials. A report from the American Society of Echocardiography's Guidelines and Standards Committee and the Task

Force on Echocardiography in Clinical Trials. American Society of Echocardiography Report. J Am Soc Echocardiography. 2004; 17(10): 1086-1119.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of testing for this patient. The California MTUS guidelines, ACOEM Guidelines and the Occupational Disability Guidelines (ODG) do not address this topic. Echocardiography is an ultrasound technique for diagnosing cardiovascular disorders. Evidence-based guidelines from the American College of Cardiology, American Heart Association, and American Society of Echocardiography outlined the accepted capabilities for Doppler echocardiography in the adult patient. Indications include those related to anatomy-pathology, color Doppler was rated as most helpful for evaluating septal defects. Among functional indications, color Doppler was considered most useful for evaluating the site of right-to-left and left-to-right shunts (Antman et al, 2003). Color Doppler was also considered useful for evaluating severity of valve stenosis and valve regurgitation and evaluation of prosthetic valves. This patient had no new complaints of unstable angina or valvular disease. In this clinical situation, this test is not warranted. Therefore, based on the submitted medical documentation, the request for 2D echocardiogram with doppler is not medically necessary.

Carotid ultrasound: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mettler: Essentials of Radiology, 2nd ed. Chapter 5-Cardiovascular System.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back, Ultrasound, Diagnostic.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this test for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of this test. Per the Official Disability Guidelines (ODG), ultrasound of the neck is not recommended for neck pain. An ultrasound of the carotid arteries can demonstrate atherosclerotic stenosis or ulceration within the common and internal carotids. An ultrasound is indicated for patients with recent transient ischemic attacks, recent cerebrovascular accidents and known peripheral atherosclerotic disease. The reason for this test is unclear. At the patient's most recent clinical encounter, peripheral pulses were documented as palpable and intact. The patient was not documented to have had a recent TIA or CVA. He also had no complaints of new neurological symptomatology. Therefore, based on the submitted medical documentation, the request for a carotid ultrasound is not medically necessary.