

Case Number:	CM14-0185348		
Date Assigned:	11/13/2014	Date of Injury:	01/01/1993
Decision Date:	12/19/2014	UR Denial Date:	10/17/2014
Priority:	Standard	Application Received:	11/06/2014

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. The expert reviewer is Board Certified in Geriatrics and is licensed to practice in New York. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 man with 50 year old man with a date of injury of January 1993. He was seen by his secondary treating physician on 9/15/14. He noted improving acid reflux and rectal bleeding for two days due to increased constipation. He as sleeping 5-6 hours per night and reported a blood pressure of 131/92 and pulse of 72. He had no chest pain or shortness of breath. He reported sexual dysfunction and low back pain. His exam showed blood pressure of 151/109 - 145/99 (on no medications). His lungs were clear and cardiac exam normal. His abdomen was soft and non-tender. His diagnoses were gastroesophageal reflux disease and antral gastritis, secondary to NSAIDs (improved), hypertension, triggered by industrial injury with left ventricular hypertrophy (uncontrolled), sleep disorder and rule out H. pylori infection. Deferred diagnoses were sexual dysfunction and aortic root dilation. He had prior labs showing a Vitamin D of 30, a urinalysis and a urine toxicology screen in 6/14. The records also indicate he had the same blood work ordered in 3/14 and 6/14. At issue in this review are labs, urine toxicology screen, urology consult "due to urinary frequency", Colace, Lovaza, Probiotics, ASA, Sentra AM, Sentra PM, Theramine and Lisinopril.

IMR ISSUES, DECISIONS AND RATIONALES

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

Labs: GI, HTN, uric acid, Vitamin D, urinalysis: 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 The Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
<http://jama.jamanetwork.com/article.aspx?articleid=1791497>

Decision rationale: At issue in this review is the request for lab work GI, HTN, uric acid, Vitamin D, urinalysis. He had a series of lab studies and a urinalysis completed in 3/14 and requested again in 6/14. His physical exam was normal and his blood pressure elevated. He had no cardiac, renal or hepatic symptoms documented. There were no historical or exam findings for toxicity or side effects of his medications. He has no history of thyroid disease, gout, anemia, renal disease, osteoporosis or diabetes. His vitamin D level was 30 in prior labs and it was not documented as being treated. He already had prior lab studies drawn within the prior several months and the medical necessity of repeat labs is not substantiated in the records.

Urine Toxicology Screen: 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)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 43, 77-78.

Decision rationale: This injured worker has a history of chronic pain. Urine drug screening may be used at the initiation of opioid use for pain management and in those individuals with issues of abuse, addiction or poor pain control. In the case of this injured workers, prior drug screening has confirmed the use of medications. The records fail to document any issues of abuse or addiction or the medical necessity of a repeat drug screen. The urine drug screen is not medically necessary.

Urology consultation: 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)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 287-310. Decision based on Non-MTUS Citation Uptodate: lower urinary tract symptoms in men

Decision rationale: This injured worker was denied a request for urologic referral. There was no documentation of any urologic symptoms or urinary frequency in the history and his physical exam was normal. It is not clear that the urinary symptoms are clearly related to his industrial injury. The records do not substantiate the medical necessity for a urology consultation.

Colace 100mg #60 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate: management of chronic constipation

Decision rationale: Docusate is a stool softener. This injured worker has had rectal bleeding due to constipation but there is no discussion of additional bowel medications or a discussion of efficacy of Colace to justify medical necessity.

Lovaza 4g (one month supply) with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Dietetic Association; 2011 Mar. 149 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate: Fish oil and marine omega-3 fatty acids

Decision rationale: This injured worker is already being treated with Lipitor. The records do not document the medical rationale for Lovaza though it is presumed it is for lipid management. The worker has a history of hypertension but no history of coronary artery disease. The medical necessity of Lovaza is not substantiated in the notes.

Probiotics #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 Maastricht IV Conference and University of Texas at Austin, School of Nursing; 2013 May. 17 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate: Probiotics for gastrointestinal diseases

Decision rationale: Probiotics are microorganisms that have beneficial properties for the host and studies suggest potential efficacy in several gastrointestinal illnesses including inflammatory bowel diseases and antibiotic-related diarrhea. This injured worker has a history of constipation and GERD. The medical records do not support the medical necessity for the use of probiotics in this injured worker.

ASA EC 81mg #30 with 2 refills: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate: Benefits and risks of aspirin in secondary and primary prevention of cardiovascular disease

Decision rationale: This injured worker has cardiac risk factors with hypertension and hyperlipidemia. However, he has no clinical symptoms of chest pain or shortness of breath. While the medication may be medically necessary, there is not a clear correlation between the industrial injury and his risk of cardiac disease or stroke to medically justify coverage for ASA.

Lisinopril 40mg #30 with 2 refills: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
<http://jama.jamanetwork.com/article.aspx?articleid=1791497>

Decision rationale: This injured worker has a history of hypertension (uncontrolled). Lisinopril would be an appropriate choice as an anti-hypertensive as an ACE-inhibitor. However, he is seen in the clinic in 9/14 with elevated blood pressure but on no medications. It is therefore difficult to assess efficacy of this medication and the medical necessity cannot be substantiated in the note.

Sentra AM #60, 3 bottles - for 3 months: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://nutrientpharmacology.com/sentra_AM.html and <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Sentra AM is a medical designed to increase and maintain the production of acetylcholine by peripheral neurons and brain cells. This injured worker has no history documented of cognitive dysfunction. Additionally, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The medical necessity for Sentra AM is not documented.

Sentra PM #60, 3 bottles - for 3 months: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate: treatment of insomnia
http://nutrientpharmacology.com/sentra_AM.html and
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Sentra PM is a medication food. Patients with insomnia should receive therapy for any medical condition that may exacerbate the problem and receive advice regarding sleep hygiene. After this, cognitive behavioral therapy would be trialed first prior to medications. In this injured worker, his sleep pattern, hygiene or level of insomnia is not addressed. Additionally, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The documentation does not support the medical necessity for Sentra PM.

Theramine #90, 3 bottles - for 3 months: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Theramine is medical food used to treat chronic pain syndromes and low back pain. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The medical necessity for Theramine is not documented.