MAXIMUS Federal Services

Case Number:	CM15-0040376		
Date Assigned:	03/10/2015	Date of Injury:	04/23/2009
Decision Date:	04/14/2015	UR Denial Date:	02/11/2015
Priority:	Standard	Application Received:	03/03/2015

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: New York, Pennsylvania, Washington
Certification(s)/Specialty: Internal Medicine, Geriatric 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 59 year old female, who sustained an industrial injury on 4/23/09. She has reported right arm, shoulder and right side of the body injury after tripping on a floor mat and falling. The diagnoses have included Gastroesophageal Reflux Disease (GERD) secondary to stress and pain medication, constipation, and suspect irritable bowel syndrome, hypertension and sleep disorder. Treatment to date has included medications, work modifications, surgery, and diagnostics. Surgery included right elbow surgery on 5/1/09. Currently, as per the physician progress note dated 1/8/15, the injured worker noted that there was improvement in her acid reflux. She denied constipation and reported she was sleeping 6 hours and waking 2-4 times a night. She continues to claim that her blood pressure is uncontrolled. Physical exam revealed blood pressure 122/82, weight 204 and height of 5 foot 3 inches. The abdomen was soft, non tender and non distended. Treatment recommendations were urine toxicology screen, carotid ultrasound and electrocardiogram (EKG), medications including Prilosec, Citrucel, Probiotics, Aspirin, Diovan , Bystolic and Hypertensa, dietary recommendations, sleep hygiene, blood pressure monitor and prescription bottles to every visit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prolisec 20mg, #30, 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 68-69.

Decision rationale: This worker has chronic pain with an injury sustained in 2009. Omeprazole or prilosec is a proton pump inhibitor, which is used in conjunction with a prescription of a NSAID in patients at risk of gastrointestinal events. Per the guidelines, this would include those with: 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). The records do not support that the worker meets these criteria or is at high risk of gastrointestinal events to justify medical necessity of omeprazole or prilosec.

Probiotics #60, 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.ncbi.nlm.nhi.gov/pubmed/22314561.

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 GERD but denies constipation currently and she has a normal abdominal exam. There is no rationale documented in the records for the probiotics nor a discussion of efficacy or side effects. The medical records do not substantiate the medical necessity for the use of probiotics in this injured worker.

Hypertensa #60, 4 bottles: 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 http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/.

Decision rationale: Hypertensa is a medical food used in hypertension and vascular health. 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 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." The records do not substantiate efficacy or side effects of hypertension nor why a medical food is being used instead of or in addition to traditional medications. The medical necessity for hypertensa is not documented.