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| Case Number: | CM15-0028980 | | |
| Date Assigned: | 02/20/2015 | Date of Injury: | 02/12/2004 |
| Decision Date: | 04/06/2015 | UR Denial Date: | 01/27/2015 |
| Priority: | Standard | Application Received: | 02/17/2015 |

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: California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 was a 65 year old female, who sustained an industrial injury, February 12, 2004. According to progress note of December 11, 2014, the injured workers chief complaint was unchanged abdominal pain. The acid reflux was well controlled with current medications. The injured worker reported occasional chest pain and weight gain. The physical exam of the abdomen noted to be soft, with normal active bowel sounds, non-tender with palpation, non-distended and np voluntary guarding. The injured worker was diagnosed with abdominal pain, gastritis, constipation and acid reflux, secondary to NSAIDS, weight gain, sleep disorder and occasional chest pain rule out cardiac verses gastrointestinal verses anxiety. The injured worker has several orthopedic diagnoses. The injured worker previously received the following treatments Prilosec, Gaviscon, Probiotics and Amitiza. December 11, 2014, the primary treating physician requested authorization for prescriptions for Prilosec 20mg #45 with 2 refills, Gaviscon with 2 refills, Probiotics #60 with 2 refills, Amitiza 8mcg with 2 refills and 1 urine drug screen. On January 27 2015, the Utilization Review denied authorization for prescriptions for Prilosec 20mg #45 with 2 refills, Gaviscon with 2 refills, Probiotics #60 with 2 refills, Amitiza 8mcg with 2 refills and 1 urine drug screen. The denial was based on the MTUS/ ACOEM and ODG guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec 20mg # 45 with 2 refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 & 9792.26, Page 68.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, prior to starting the patient on a proton pump inhibitor, physicians are asked to evaluate the patient and to determine if the patient is at risk for gastrointestinal events. Criteria used are: (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. There is documentation that the patient has a risk factor needed to recommend the proton pump inhibitor Prilosec. The patient is 65 years old. Prilosec 20mg # 45 with 2 refills is medically necessary.

Unknown prescription of Gaviscon with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitor (PPI).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Gaviscon U.S. home page. GlaxoSmithKline.

Decision rationale: Gaviscon is a non-prescription medicine, which is taken by mouth to treat heartburn and gastroesophageal reflux disease (GERD). The MTUS and the Official Disability Guidelines are silent on Gaviscon. The manufacturer's website was referenced. The Gaviscon is a safe and fairly effective method of treating gastroesophageal reflux disease. The requesting provider fails to quantify the amount of medication requested for authorization. Unknown prescription of Gaviscon with 2 refills is not medically necessary.

Probiotics #60 with 2 refills: 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 Official Disability Guidelines, Pain (Chronic), Medical food.

Decision rationale: Probiotics are microorganisms that provide health benefits when consumed, as claimed by some. The term probiotic is currently used to name ingested microorganisms associated with beneficial effects to humans and animals. Probiotics are currently considered a medical food. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered entirely 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Probiotics #60 with 2 refills is not medically necessary.

Amitiza 8mcg #90 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 Institute for Health and Care Excellence (NICE). Lubiprostone for treating chronic idiopathic constipation. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jul.48p.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 & 9792.26, Page 77.

Decision rationale: Amitiza (lubiprostone) is approved by the FDA for the treatment of chronic constipation of unknown cause in adults, as well as irritable bowel syndrome associated with constipation. The patient does not suffer from idiopathic constipation. The cause of the patient's constipation is known to be opioid-induced. Amitiza 8mcg #90 with 2 refills is not medically necessary.

Urine drug 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, Pain (Chronic).

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

Decision rationale: The MTUS recommends using a urine drug screen to assess for the use or the presence of illegal drugs, a step to take before a therapeutic trial of opioids, to aid in the ongoing management of opioids, or to detect dependence and addiction. There is no documentation in the medical record that a urine drug screen was to be used for any of the above indications. Urine drug screen is not medically necessary.