

Case Number:	CM14-0062876		
Date Assigned:	07/14/2014	Date of Injury:	03/01/2007
Decision Date:	09/10/2014	UR Denial Date:	04/07/2014
Priority:	Standard	Application Received:	05/05/2014

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 Occupational Medicine, and is licensed to practice in California. 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:

Patient is a 58 year-old female with date of injury 03/01/2007. The medical document associated with the request for authorization, a primary treating physician's progress report, dated 03/25/2014, lists subjective complaints as abdominal pain which is controlled by medications and acid reflux which is controlled by medications. Objective findings: Examination of the abdomen revealed it to be soft with normal active bowel sounds. No tenderness to palpation or guarding was noted. Diagnoses: 1. Abdominal Pain, 2. Acid Reflux, 3. Diarrhea, 4. Blurred Vision, 5. Hypertension, and 6. Shortness of breath. The medical records provided for review document that the patient has been taking the following medications for at least as far back as 3 months. Medications are: 1. Simethicone 80mg, #90 SIG: twice daily 2. Probiotics, #90 SIG: twice daily

IMR ISSUES, DECISIONS AND RATIONALES

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

Simethicone 80 mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System; 2012 May.page 12.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:http://www.hopkinsmedicine.org/healthlibrary/conditions/digestive_disorders/gas_in_the_digestive_tract_85,P00369/.

Decision rationale: Simethicone is an orally administered anti-foaming agent used to reduce bloating, discomfort or pain caused by excessive gas in the stomach or intestines. Simethicone is a mixture of polydimethylsiloxane and hydrated silica gel. The most common adverse effects of Simethicone are gastrointestinal symptoms, including mild diarrhea, nausea, regurgitation, and vomiting. The MTUS and Official Disability Guidelines are silent on Simethicone. According to the above-mentioned reference from Johns Hopkins Reference Library concerning digestive disorders, Simethicone is not recommended for acid reflux disorder, and may actually increase the patient's symptoms of diarrhea. Therefore, the request is not medically necessary.

Probiotics #90: 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 (ODG) 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 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. 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. Therefore the request is not medically necessary.