

<b>Case Number:</b>	CM14-0049445		
<b>Date Assigned:</b>	07/09/2014	<b>Date of Injury:</b>	07/06/2007
<b>Decision Date:</b>	10/15/2014	<b>UR Denial Date:</b>	03/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/17/2014

### 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 Emergency Medicine, has a subspecialty in Emergency Medical Services and is licensed to practice in Texas. 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 57-year-old female who reported an injury on 07/06/2007 due to an exposure to chemicals and lifting greater than 40 pounds. Clinical note reveals no complaints. The diagnoses included possible hemorrhoids, constipation/diarrhea, gastritis, internal hemorrhoids, and diabetes mellitus, sleep disorder, hypertension, and increased uric acid. The physical examination of the abdomen revealed obesity was noted, soft, no tenderness to palpation, no hepatosplenomegaly on exam, and no guarding; notes dated 03/19/2014. The treatment plan included urine toxicology screening. Medications included Prilosec #30, Gaviscon, Miralax, Colace, TriCor, metformin, glipizide, probiotics, aspirin, Preparation H, gemfibrozil, Cozaar, and Bystolic. Request for Authorization dated 07/09/2014 was submitted with documentation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Probiotics # 60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**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: [www.ncbi.nlm.nih.gov/pubmed/18181719](http://www.ncbi.nlm.nih.gov/pubmed/18181719)

**Decision rationale:** The request for Probiotics #60 is not medically necessary. The California MTUS/ACOEM or the Official Disability Guidelines do not address. The US Food and Drug Administration regulatory categorization indicates that probiotics are living microorganisms that, when consumed, have the potential to confer a beneficial health effect. Unfortunately for purveyors of probiotic products, the system of regulation delineated in the Food, Drug, and Cosmetic Act is anything but "one size fits all." How a probiotic product is used or is intended to be used will govern the regulatory category or categories that the US Food and Drug Administration (FDA) will assign to the product. The extent and nature of the restraints and data-collection requirements that may be imposed on the marketing of a product hinge on how a product is categorized under the Act. More specifically, the categorization of a product governs the respective regulatory burdens of an industry sponsor and the FDA. Premarket systems, such as those for new drugs and biologics, place a heavy evidentiary burden on the sponsor of a product. Postmarket systems, such as those for dietary supplements, place, at least initially, a higher regulatory evidentiary burden on the FDA than on the product sponsor. This article explains regulatory categorizations under the Food, Drug, and Cosmetic Act and their effects regarding the federal regulation of probiotic products. The request did not indicate the dosage or the frequency. The guidelines do not address the probiotics. As such, the request is not medically necessary.