

<b>Case Number:</b>	CM14-0024332		
<b>Date Assigned:</b>	06/11/2014	<b>Date of Injury:</b>	09/25/2002
<b>Decision Date:</b>	07/29/2014	<b>UR Denial Date:</b>	02/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/26/2014

### 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 Physical Medicine & Rehabilitation 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:

This is a 65-year-old female with the date of injury of 9/25/02. The initial mechanism of injury was being struck in the back by a door handle. From this initial mechanism of injury, there are multiple injured body parts/diagnoses that include headaches, s/p right knee arthroscopy, and left TKA and GI issues. She has been referred to an internist and gastroenterologist, who have diagnosed her with gastroesophageal reflux disease, irritable syndrome, and history of H. pylori treatment. As of 1/20/14, the GI specialist stated that she was at maximal medical improvement from a GI perspective. 12/17/13 report indicates that the patient is on Atenolol, Prilosec, Gaviscon, Colace, Simvastatin, Probiotics, ASA and Theramine. Multiple requests were submitted to Utilization Review with an adverse decision on these items rendered on 2/03/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**URINE TOXICOLOGY SCREEN TEST:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Urine drug testing (UDT).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 85, and 94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Urine drug testing (UDT).

**Decision rationale:** Guidelines clearly support use of urine drug screening/toxicology for the purpose of monitoring compliance, identifying undisclosed substances, and uncovering diversion of prescribed substances. For moderate risk patients, 2-3 tests per year are adequate. More frequent testing may be required for higher risk patients, or when there are inconsistencies. This testing is done for patients on opioid medications. In this case, the patient is not taking any opioid pain medications or any other controlled substances/medications with a dependency profile. There is no medical necessity for urine toxicology testing.

**PROBIOTICS #60 TWICE DAILY (TWO 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.nih.gov/pubmedhealth/PMHT0012124/?report=details#uses>.

**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: Clinical indications for probiotics: an overview. Goldin BR, Gorbach SL. Clin Infect Dis. 2008 Feb 1;46 Suppl 2:S96-100; discussion S144-51. doi: 10.1086/523333.

**Decision rationale:** The CA MTUS, ACOEM and ODG are silent on use of probiotics, therefore, consider the above published by the NIH. Probiotic bacteria are used to treat or prevent a broad range of human diseases, conditions, and syndromes. In addition, there are areas of medical use that have been proposed for future probiotic applications. Randomized double-blind studies have provided evidence of probiotic effectiveness for the treatment and prevention of acute diarrhea and antibiotic-induced diarrhea, as well as for the prevention of cow milk-induced food allergy in infants and young children. Research studies have also provided evidence of effectiveness for the prevention of traveler's diarrhea, relapsing *Clostridium difficile*-induced colitis, and urinary tract infections. There are also studies indicating that probiotics may be useful for prevention of respiratory infections in children, dental caries, irritable bowel syndrome, and inflammatory bowel disease. Areas of future interest for the application of probiotics include colon and bladder cancers, diabetes, and rheumatoid arthritis. The probiotics with the greatest number of proven benefits are *Lactobacillus rhamnosus* strain GG and *Saccharomyces boulardii*. In this case, use of probiotics would be considered investigational, as there are no clear studies that reflect use of probiotics for the treatment of GERD and IBS is as effective as or more effective than current standard of care treatments for these conditions. Medical necessity for probiotics is not established.

**THERAMINE #60, THREE BOTTLES:** 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), Pain Chapter.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 125. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical food.

**Decision rationale:** The CA MTUS and ACOEM 2nd edition are silent on medical foods, but the 2nd revised Low back chapter does address use of Theramine. This is considered a medical food or complementary/alternative treatment, and not recommended by ACOEM. This opinion is corroborated by ODG, which also does not recommend medical foods, unless there is clear documentation of a true deficiency with medical necessity for supplementation of the documented deficiency. In addition, there is no clear medical necessity to compound a prescription medication with a supplement. Medical necessity for Theramine is not established.