

<b>Case Number:</b>	CM13-0020572		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	02/07/2005
<b>Decision Date:</b>	03/26/2014	<b>UR Denial Date:</b>	08/28/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/05/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice 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 physician 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 patient is a 43-year-old male who reported injury on 02/07/2005. The mechanism of injury was not provided. The patient was noted to be complaining of right knee pain. The patient was noted to have a continuous problem with constipation, and indicated that Metamucil, senna, and Miralax did not work, so the patient was noted to start taking as probiotics over-the-counter at a general health store on his own, and indicated that it had been effective with treating the constipation, and the patient indicated additionally, he was taking prune juice. The patient was noted to stop taking the probiotics, and the patient was noted to become constipated again. As such, the patient restarted the probiotics and the constipation was resolved. The patient's diagnoses are noted to include degenerative lumbar disc disease, right knee pain, depression, anxiety, and insomnia. The request was made for Culturelle.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Culturelle:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain Page(s): 80-82.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Initiation of Opioid Therapy Page(s): 77.

**Decision rationale:** California MTUS Guidelines indicate that when initiating opioid therapy, prophylactic treatment of constipation should be initiated. The patient was noted to have a continuous problem with constipation, and indicated that Metamucil, Senna, and Miralax did not work, so the patient was noted to start taking as probiotics over-the-counter at a general health store on his own, and indicated that it had been effective with treating the constipation, and the patient indicated additionally, he was taking prune juice. The patient was noted to stop taking the probiotics and he reported that he became constipated again. The patient stated that he then restarted the probiotics and the constipation was resolved. The patient was noted to be on Duragesic and Norco, as well as oxycodone. Culturelle would be considered a medical food. Official Disability Guidelines indicates that medical foods are "a food which is formulated to be consumed or administered enterally 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...To be considered the product must, at a minimum, meet the following criteria...the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements". Clinical documentation submitted for review indicated the patient found the medication to be efficacious, however, it has not been approved nor labeled by the FDA to treat a particular disease per drugs.com. Additionally, the request as submitted was for an undetermined strength and an undetermined quantity of medication. Given the above, the request for Culturelle is not medically necessary.