

<b>Case Number:</b>	CM15-0139561		
<b>Date Assigned:</b>	07/29/2015	<b>Date of Injury:</b>	08/05/1998
<b>Decision Date:</b>	09/15/2015	<b>UR Denial Date:</b>	07/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/20/2015

### 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: Physical Medicine & Rehabilitation, Pain Management

### 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 51 year old female, who sustained an industrial injury on 8.5.98. Initial complaints were of repetitive type injury to neck, wrists-hands and back. The injured worker was diagnosed as having abdominal pain; acid reflux; constipation; hypertension; bright blood per rectum; blurred vision; shortness of breath; migraine headaches. Treatment to date has included chiropractic therapy; status post carpal tunnel release (2000); physical therapy; psychiatric evaluation and counseling; medications. Diagnostics studies included CT scan abdomen (1/12/2015). Currently, the PR-2 notes dated 5.20.15 indicated the injured worker reports improving abdominal pain, constipation, denies blood in her stool and stable blood pressure. Medications are listed by this provider as HCTZ 25mg; Nexium 40mg; ASA 81mg - each daily and Carafate 1g four times daily, Probiotics twice a day and digestive enzymes and Albuterol inhaler. He has recommended an ophthalmology consultation to rule out end-organ damage secondary to hypertension and a gastrointestinal consultation secondary to occasional bright blood per rectum and dysphagia. The provider recommended a course of sleep hygiene and increase fluids for regular bowel movements. He advised the injured worker to follow-up with her primary treating physician and return to this office in three months to review diagnostic studies. The injured worker has a clinical and surgical history of herniated disc to the lower back and neck. She has been treated for hypertension, musculoskeletal pain, carpal tunnel release, occipital nerve stimulator implant; long-term drug use; uses a walker for ambulation and has had psychiatric evaluation and counseling. The provider is requesting authorization of ASA 81mg #30; Digestive Enzymes; Nexium 40mg #30 and Probiotics #60.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Nexium 40mg #30:** Upheld

**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 PPIs Page(s): 68 and 69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, PPI.

**Decision rationale:** Regarding the request for Nexium, California MTUS states that proton pump inhibitors are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Additionally, ODG recommends Nexium, Protonix, Dexilant, and AcipHex for use as 2nd line agents, after failure of omeprazole or Lansoprazole. Within the documentation available for review, there is documentation of acid reflux and abdominal pain. However, there is no indication that the patient has failed first-line agents prior to initiating treatment with Nexium (a 2nd line proton pump inhibitor), which is prefer over Nexium. As such, the currently requested Nexium is not medically necessary.

**Probiotics #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.drugs.com/drugs-class/probiotics](http://www.drugs.com/drugs-class/probiotics).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [http://cid.oxfordjournals.org/content/46/Supplement\\_2/S96.long](http://cid.oxfordjournals.org/content/46/Supplement_2/S96.long).

**Decision rationale:** Regarding the request for probiotics, CA MTUS and ODG do not address the issue. A search of the National Library of Medicine and other online resources reveals that Proven benefits of probiotics include the treatment of acute and antibiotic-associated diarrhea; applications with substantial evidence include the prevention of atopic eczema and traveler's diarrhea; promising applications include the prevention of respiratory infections in children, prevention of dental caries, elimination of nasal pathogen carriage, prevention of relapsing C. difficile-induced gastroenteritis, and treatment of inflammatory bowel disease; and proposed future applications include the treatment of rheumatoid arthritis, treatment of irritable bowel syndrome, cancer prevention, prevention of ethanol-induced liver disease, treatment of diabetes, and prevention or treatment of graft-versus-host disease. The use of probiotics in medical practice is rapidly increasing, as are studies that demonstrate the efficacy of probiotics. A note of caution should be applied: negative findings are being reported, as would be expected as more studies are being performed and as more applications are being sought for the use of probiotics. Within the documentation available for review, there is no clear identification of the condition(s) for which the probiotics are being utilized and evidence-based support for the use of probiotics in the management of that/those condition(s). In the absence of clarity regarding the above issues, the currently requested probiotics are not medically necessary.

**ASA 81mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-72.

**Decision rationale:** Regarding the request for Aspirin, Chronic Pain Medical Treatment Guidelines state that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Within the documentation available for review, the patient has documented GERD symptoms, as well as documentation of GI bleed with bright red blood per rectum. For these reasons, use of aspirin is contraindicated. Therefore, the currently requested Aspirin is not medically necessary.

**Digestive Enzymes:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.drugs.com/drug-class/digestive-enzymes](http://www.drugs.com/drug-class/digestive-enzymes).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.webmd.com/drugs/2/drug-673/digestive+enzymes+oral/details#uses>.

**Decision rationale:** Regarding digestive enzymes, CA MTUS and ODG do not address the issue. WebMD states this medication contains digestive enzymes, which are natural substances needed by the body to help break down and digest food. It is used when the pancreas cannot make or does not release enough digestive enzymes into the gut to digest the food. Depending on the amount of enzymes, it may be used for indigestion, as a supplement, or as replacement therapy (e.g., in chronic pancreatitis, cystic fibrosis, cancer of the pancreas, after surgery on the pancreas or gut). Some supplement products have been found to contain possibly harmful impurities/additives. The FDA has not reviewed this product for safety or effectiveness. Within the documentation available for review, there is no clear identification of the condition(s) for which the digestive enzymes are being utilized. Furthermore, the FDA has not reviewed this product for its safety profile. As such, the currently requested the digestive enzymes are not medically necessary.