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| <b>Case Number:</b>   | CM13-0039311 |                              |            |
| <b>Date Assigned:</b> | 12/18/2013   | <b>Date of Injury:</b>       | 04/13/2009 |
| <b>Decision Date:</b> | 02/28/2014   | <b>UR Denial Date:</b>       | 10/01/2013 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/04/2013 |

### 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 Pain Management, has a subspecialty in Disability Evaluation 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:

On April 13, 2009, the patient was working on a glass polish machine, rebuilding spindles, which he had worked on all day by himself. At about 2:00 pm the patient was doing the final adjustment of the belt tension when his boss, came up to him. He was told that the patient was near to overtime and to lift the motor up by hand and he would tighten the bolts up for the patient. When the patient lifted up on the motor, it powered up, ripping off the tip of his left middle finger and crushing his ring finger. The patient immediately grabbed his hand by putting pressure on it. The head of safety and transportation, took the patient to the company clinic and left. His boss came up 20 minutes later and brought what was left of the patient's finger. The clinic scheduled the patient for immediate surgery with [REDACTED] in [REDACTED] and was rushed there. The patient relates that he received no pain medications or ice pack but a bandage over the exposed bone. Thereafter, the patient consulted [REDACTED] and checked in for surgery. [REDACTED] amputated down to his first joint on his left middle finger and placed a splint on the left ring finger. The patient thought that he sustained minor injuries only and that he would be back to normal in a month or so. But, as it healed, the patient began to experience severe pain. He was off work for one and a half months but continued to have pain. [REDACTED] released the patient to work on light duties but no light duties were available on his job. The patient went back to work anyway and did full duties despite the pain. [REDACTED] eventually suggested neurectomy to hopefully remove the neuromas and eliminate the pain. On June 30, 2009, the patient underwent neurectomy as an outpatient and went off work for about a month. Thereafter, the patient went back to full duties at work. [REDACTED] ordered physical therapy but the patient never had it until two and a half months later. The patient states that his ring finger healed correctly but his middle finger did not. He continued to have severe pain. In October 2009, the patient had another neurectomy. He was put off work until January 2010. In February 2010, [REDACTED].

discussed another surgery with the patient but he refused. The patient has cortisone shot and sought for a second opinion, which recommended amputating again and moving nerves to palm. In May 2010, the patient had another surgery. He was off work for one week. Things went even worse, half of his finger died and his pain increased. The patient had five skin grafts to save what was left of his finger but continued to have pain. His pain medications have only helped minimally. He was placed off work since May 13, 2010. The patient started pain management in November 2010, and stellate ganglion block and different medications were suggested. It took two and a half months to start this process. The patient received the first block on January 31, 2011. The doctor sent a request for three more blocks to be performed one after the other in two weeks but the patient's office only approved two blocks, which were not scheduled right away. After the last two blocks, the doctor requested for another three more blocks but was denied because of lack of improvement. Thus, the patient became extremely irritable. The patient has lost interest in doing numerous things because of pain in everything he does. At present, the patient is receiving continuing treatment with and . The patient is waiting for approval for surgery in the form of ray-resection for the left mid finger. 9/17/13 medical report state that the patient had significant improvement with the FRP program. He continues to have sleep issues. Melatonin and Canela tea have not been helpful. Benadryl has not been helpful. He is currently on Neurontin, Lidoderm, Omeprazole and Cymbalta. Diagnosis are complex regional pain syndrome (CRPS), status post left the third finger amputation, opioid dependence with

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Relora:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG);

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation United States Food and Drug Administration (USFDA): BMC Open Access Publishers.

**Decision rationale:** The California Medical Treatment Utilization Section (MTUS) (Effective July 18, 2009) is mute on Relora. A recent abstract published on line in BMC (BIOMEDCentral) an open access publisher indicated that Magnolia (*Magnolia officinalis*) and Phellodendron (*Phellodendron amurense*) barks are medicinal plants commonly used as traditional remedies for reducing stress and anxiety. Modern dietary supplements are intended to induce relaxation and reduce stress as well as stress-related eating. Previous studies have shown the combination of Magnolia/Phellodendron (MP) to reduce both cortisol exposure and the perception of stress/anxiety, while improving weight loss in subjects with stress-related eating. Competitive athletes are "stressed" by their intense exercise regimens in addition to their normal activities of daily living and thus may benefit from a natural therapy intended to modulate baseline perceptions of stress and stress hormone exposure. These results indicate that daily supplementation with a combination of Magnolia bark extract and Phellodendron bark extract (Relora®) reduces cortisol exposure and perceived daily stress, while improving a variety of

mood state parameters, including lower fatigue and higher vigor. These results suggest an effective natural approach to modulating the detrimental health effects of chronic stress in moderately stressed adults. Future studies should examine the possible performance and recovery benefits of Relora supplementation in athletes overstressed by the physical and psychological demands of training and competition. According to USFDA website, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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. Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval. There was no documentation of such a specific medical disorder, disease, or condition for a distinctive nutritional requirement for Relora. Therefore the request for Relora as a sleep aid is not medically necessary.