

<b>Case Number:</b>	CM14-0128370		
<b>Date Assigned:</b>	08/15/2014	<b>Date of Injury:</b>	09/08/2008
<b>Decision Date:</b>	11/28/2014	<b>UR Denial Date:</b>	08/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/12/2014

### 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 Family Medicine 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 51-year-old male who reported an industrial injury to the neck, back, and elbows on 9/8/2008, over six (6) years ago, attributed to the performance of his usual and customary job duties. The patient continued to complain of bilateral elbow pain, cervical spine pain; and lumbar spine pain. The patient received an internal medicine consultation for his blood pressure, GERD allegedly due to medications; struct of sleep apnea; insomnia; blurred vision; and anxiety/depression. The objective findings on examination were documented as normal. The patient was diagnosed with hypertension, hyperlipidemia, shortness of breath secondary anxiety, abdominal pain, acid reflux secondary to stress, rule out ulcer/anatomical alteration, weight gain, sleep disorder, rule out obstructive sleep apnea, mitral stenosis, gastritis, and pterygium. The patient was prescribed hydrochlorothiazide; Lisinopril; Dexilant, Gaviscon, Carafate, probiotics, aspirin, Medroxcin patches, Hypertensa, Sentra AM.; Sentra PM; and topical compounded creams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Hypertensa #60:** 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, Medical food

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

**Decision rationale:** Hypertensa is a prescription medical food formulated for the nutritional management of hypertension and other vascular diseases. The hypertensa formula promotes nitric acid production in the blood vessels. Patients with hypertension may have increased nutritional requirements of arginine, choline, and certain antioxidants. Patients with hypertension have reduced plasma levels of arginine and have been shown to respond to oral administration of arginine. Patients with hypertension have activation of arginine's pathway that diverts arginine from production of nitric oxide to production of deleterious nitrogen molecules such as Peroxynitrite. The process increases the turnover rate of arginine resulting in increased requirement for arginine. Since arginine is a semi-essential amino acid, produced by the liver, the increased turnover rate leads to an arginine deficient in hypertension. The prescribing physician is speculated that the patient has reduced arginine levels based on the diagnosis of hypertension. It is noted that the patient is prescribed other oral antihypertensives but is also prescribed this medical food in order to treat the diagnosed hypertension. It is not clear how hypertension is directly or indirectly related to the cited mechanism of injury related to neck, back, and elbow pain. The patient is not been demonstrated to have reduced arginine levels and the treatment of the diagnosis of hypertension with Hypertensa is not demonstrated to be medically necessary. The patient is not been demonstrated to have a nutritional deficit or an arginine deficiency to support the medical necessity of a prescription for amino acids in the form of a medical food. Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." Therefore, the Hypertensa #60 is not medically necessary and appropriate.