

<b>Case Number:</b>	CM13-0025641		
<b>Date Assigned:</b>	11/20/2013	<b>Date of Injury:</b>	11/26/2008
<b>Decision Date:</b>	02/14/2014	<b>UR Denial Date:</b>	08/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/17/2013

### 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:

The patient is a 62-year-old male who was injured on 11/26/2008. The patient describes the injury as having occurred when he stepped onto a pallet in order to reach a box of meat when his right foot got caught between the wood spaces. He related that he lost his balance and fell hard over his right side and then onto his back. The patient noted immediate pain all over his right arm and mild discomfort in his lower back when he stepped off of the truck. On that same day the patient presented to the Emergency Room at [REDACTED] in [REDACTED]. He received medication in the form of Motrin and was advised to follow up with the company doctor. On December 1, 2008 the patient was evaluated at [REDACTED] where radiographs of his right shoulder and forearm were obtained. He was diagnosed with work related right elbow/arm contusion. He was prescribed Cyclobenzaprine and Biofreeze as well as a course of physical therapy 3 times per week for two weeks. On January 5, 2009 he came under the care of [REDACTED], an orthopedic surgeon at [REDACTED]. He was diagnosed with multilevel lumbar degenerative disc disease with associated lumbar facet syndrome; and right elbow contusion with slow resolution of flexor Tenosynovitis of the volar flexor tendon. He was prescribed medication in the form of Relafen and Darvocet. He was advised to continue with physical therapy two times a week for four weeks. A magnetic resonance imaging scan of the lumbar spine was obtained on March 10, 2009 it revealed mild bilateral, neural foraminal stenosis at L5-S1 secondary to a 4.00 broad based disco protrusion; minimal central canal stenosis and minimal to mild bilateral neural foraminal stenosis at L4-5 secondary to a 5 mm broad based disc herniation; and, bilateral spondylolysis is noted at L5-S1 with Grade 1 spondylolisthesis. On February 16, 2010 the patient was provided with a lumbar epidural steroid injection. The patient received 50% relief

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Fluoxetine 20 mg #30: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 15.

**Decision rationale:** The California MTUS Guidelines, page 15 states that Fluoxetine (Prozac) is used to treat depression, obsessive-compulsive disorder (bothersome thoughts that won't go away and the need to perform certain actions over and over), some eating disorders, and panic attacks (sudden, unexpected attacks of extreme fear and worry about these attacks). Fluoxetine (Sarafem) is used to relieve the symptoms of premenstrual dysphoric disorder, including mood swings, irritability, bloating, and breast tenderness. Fluoxetine is in a class of medications called selective serotonin reuptake inhibitors (SSRIs). It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance. This medication is being used to treatment early morning depression according to treating psychiatrist, therefore the request for Fluoxetine 20 mg #30 is medically necessary.

### **Gabadone #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation USFDA Information on Medical Foods. Journal of Central Nervous Disease 2012: 4:65-72. Published online 2012 April 23. Doi: 10.4137/JCNSD.S9381.

**Decision rationale:** 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 to require a diet supplement such as Gabadone. Therefore the request for Gabadone #60 is not medically necessary.

### **Sentra AM #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation USFDA Information on Medical Foods. Journal of Central Nervous Disease 2012: 4:65-72. Published online 2012 April 23. Doi: 10.4137/JCNSD.S9381

**Decision rationale:** 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 to require a diet supplement. Therefore the request for Sentra AM #60 is not medically necessary.

**Sentra PM #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation USFDA Information on Medical Foods. Journal of Central Nervous Disease 2012: 4:65-72. Published online 2012 April 23. Doi: 10.4137/JCNSD.S9381.

**Decision rationale:** 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 to require a diet supplement. Therefore the request for Sentra PM #60 is not medically necessary.

**Theramine #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation USFDA Information on Medical Foods. Journal of Central Nervous Disease 2012: 4:65-72. Published online 2012 April 23. Doi: 10.4137/JCNSD.S9381.

**Decision rationale:** 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 is no documentation by the treating physician that this patient cannot use conventional diets or supplements, therefore the prescription of Theramine is not medically necessary.