

<b>Case Number:</b>	CM13-0037349		
<b>Date Assigned:</b>	12/20/2013	<b>Date of Injury:</b>	08/01/2007
<b>Decision Date:</b>	02/20/2014	<b>UR Denial Date:</b>	09/23/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/23/2013

### 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 claimant is a 49 year old female who indicates that from August 2007 to August 17, 2008, she developed pain in her right knee, right shoulder, lower back, upper back, bilateral hands/wrist which she attributes to repetitive work, such as sewing denim prolonged sitting, walking and standing. In December 2007, she indicates that she was walking outside to her lunch area, while it was raining, when she slipped. She indicates that she landed on her bilateral knees. She reported the injury to her manager, [REDACTED], but no medical care was offered. On August 17, 2008, she was terminated. She developed depression, stress, anxiety, and sleeping problems, which she attributes to pain. She indicates sleeping four to five hours and waking up three times per night. She denies undergoing a sleep study or taking sleep medication. In October 2008, she sought legal representation with attorney [REDACTED], who referred her to an unrecalled doctor, who ordered X-rays and an MRI of her right shoulder, bilateral knees, lower back and right wrist. The results revealed torn tendon in her right shoulder, torn meniscuses in her right knee, and six dislocated discs in her lower back. She received physical therapy, acupuncture, electric wave therapy, and chiropractic care for an unrecalled amount of time, which provided temporary relief. In approximately 2009 she was following with her general practitioner, [REDACTED], due to her diabetes and high cholesterol. She was initially diagnosed in 1995 and was taking Zetia and insulin-R 55 units. She was prescribed additional insulin-N 125 units. She attributes the aggravation of her diabetes to pain and stress. On average, her glucose level is 140-150 mg/dL. In 2009, she was referred to an unrecalled psychologist, who evaluated her. She received individual therapy sessions for an unrecalled amount of time. In 2010, she was diagnosed with hypertension by an unrecalled doctor, which she attributes to pain and stress. She was prescribed lndap

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Pharmacy:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical/Compounded Medications Page(s): 121-122.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113 of 127. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Procedure Summary- Pain. on page 1077. The USFDA and Daily Med was also used as other medical evidence

**Decision rationale:** CA-MTUS(Effective July 18, 2009) is MUTE on this Theratramadol therapy. Official Disability Guidelines, Procedure Summary- Pain. on page 1077 and USFDA, as "a food which is formulated to be consumed or administered enterally under the supervision of a physician 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, a minimum, meet the following criteria: 1) the product must be a food for oral or tube feeding; 2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; 3) the product must be used under medical supervision." TheraTramadol is a Compound agent consisting of Theramine ( a medical food - non drug) and Tramadol (a synthetic opioid agonist- drug) According to CA-MTUS(Effective July 18, 2009) page 113 of 127, regarding Tramadol states as follows : Tramadol (Ultram<sup>®</sup>) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. According to Daily Med, Primary Ingredients of Theramine consists of a proprietary formulation of Gamma Aminobutyric Acid, Choline Bitartrate, Whey Protein Hydrolysate, L-Arginine, L-Histidine, L-Glutamine, Theobromine, Griffonia See, Grape Seed, L-Serine, and Cinnamon in specific proportions. These ingredients fall into the classification of Generally Recognized as Safe (GRAS) as defined by the Food and Drug Administration (FDA) (Sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act). A GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use. The standard for an ingredient to achieve GRAS status requires not only technical demonstration of non-toxicity and safety, but also general recognition of safety through widespread usage and agreement of that safety by experts in the field. Many ingredients have been determined by the FDA to be GRAS, and are listed as such by regulation, in Volume 21 Code of Federal Regulations (CFR) Sections 182, 184, and 186. According to RFA from Dr Herbert Harshak dated 10/24/2013, who stated: "As you are aware, the patient is diagnosed with (a) abdominal pain, rule out gastritis, rule out gastric and duodenal ulcers, (b) constipation, rule out irritable bowel syndrome, (c) dysphagia, rule out structural, {d} gastro esophageal reflux disease, (e) abnormal liver function tests, and {f} fatty liver ". "Theramine is a medical food that will potentiate the effects of the patient's oral medications (including Tramadol) by increasing its absorption in the gastrointestinal tract.. Moreover. this medical food will stimulate production of neurotransmitters including serotonin, GABA, nor epinephrine. nitric oxide and acetylcholine, in order to help mana

