

Case Number:	CM15-0138652		
Date Assigned:	09/10/2015	Date of Injury:	05/19/2008
Decision Date:	10/08/2015	UR Denial Date:	07/06/2015
Priority:	Standard	Application Received:	07/17/2015

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive Medicine

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 61 year old female, who sustained an industrial injury on May 19, 2008, incurring right shoulder injuries. She underwent two shoulder surgeries and right carpal tunnel release. She had no prior injuries to her shoulder. She was diagnosed with a right shoulder sprain and right carpal tunnel syndrome. The injured worker incurred further injuries at another time to her low back. Treatment for the right shoulder included chiropractic sessions, physical therapy and home exercise program, anti-inflammatory drugs, muscle relaxants, pain medications, proton pump inhibitor, neuropathic medications, antidepressants, topical analgesic cream, transcutaneous electrical stimulation unit and work restrictions with modifications. Currently, the injured worker complained of ongoing right shoulder pain radiating to the entire arm from the elbow to the hand. She noted tenderness and spasms to the cervical and trapezius muscles with limited range of motion. She had decreased sensation of the right thumb, index and middle fingers. The treatment plan that was requested for authorization on July 14, 2015, included prescription for Theramine and Gabapentin, Lidocaine, Flurbiprofen, Capsaicin, Menthol, Ketoprofen (GLFCMK) compound cream. On July 6, 2015, the request for topical analgesic compound cream was denied by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: 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 (online version), Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Theramine and medical food.

Decision rationale: ODG states that a medical food 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". ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-Arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain." See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." The ODG guidelines do not support the use of Theramine. As such the request for Theramine #90 is not medically necessary.

GLFCMK cream x2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

Decision rationale: MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical

product.” Topical cyclobenzaprine is not indicated for this usage, per MTUS. MTUS states that topical Gabapentin is “Not recommended.” And further clarifies, “antiepilepsy drugs: There is no evidence for use of any other antiepilepsy drug as a topical product.” As such, the request for GLFCMK cream x2 is not medically necessary.