

Case Number:	CM15-0118927		
Date Assigned:	06/29/2015	Date of Injury:	10/27/2005
Decision Date:	08/04/2015	UR Denial Date:	06/05/2015
Priority:	Standard	Application Received:	06/19/2015

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: Texas, California

Certification(s)/Specialty: Family Practice

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 58 year old female who sustained an industrial injury on 10/27/05. Initial complaints and diagnoses are not available. Treatments to date include medications, acupuncture, and therapy. Diagnostic studies are not addressed. Current complaints include right sided spasm to the neck and shoulder. Current diagnoses are not available. In a progress note dated 05/20/15 the treating provider reports the plan of care as a home exercise program and medications including Theramine, Sentra PM, Sentra AM, and Lidocaine patches. The physical examination of the right shoulder revealed full ROM and strength and tenderness on palpation. The physical examination of the neck and back revealed decreased. ROM and sensation and no tenderness on palpation and 5/5 strength. The patient has had depression and lack of energy. The requested treatments include Theramine and Medi Patches. The patient sustained the injury in a MVA. The patient has had UDS on 5/20/15 that was negative for opioid.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine 62.5-100 MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines (ODG), Treatment Index, 8th Edition (web), Pain (updated 07/15/15), Theramine, Medical foods.

Decision rationale: Request: Theramine 62.5-100 MG #90. Theramine is a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). Per the cited guidelines, theramine is "Not recommended. Theramine is a medical food from [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." Therefore, these products still have limited scientific evidence for efficacy and safety profile for the management of pain. ACOEM and CA MTUS does not address these medications. The contents of these medical food products are not recommended by ODG. According to the ODG guidelines, 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. ODG quoting the FDA specifically states, To be considered the product must, at a minimum, meet the following criteria: (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The response to other pharmacological measures for treatment of pain was not specified in the records provided. There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. Therefore, there is no medical necessity for any medication containing these food supplements. Any evidence of nutritional deficiency of the contents of this product was not specified in the records provided. The medical necessity of the request for Theramine 62.5-100 MG #90 is not fully established in this patient. Therefore, the request is not medically necessary.

Medi-Patch .5 Percent-20 Percent #10 with 3 Refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines page 111-112, Topical Analgesics Lidoderm (lidocaine patch) page 56-57.

Decision rationale: Medi-Patch .5 Percent-20 Percent #10 with 3 Refills. According to the MTUS Chronic Pain Guidelines, regarding topical analgesics state that the use of topical analgesics is "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents." According to the MTUS Chronic Pain Guidelines "Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. A failure of a trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications is not specified in the records provided. Any evidence of post-herpetic neuralgia is not specified in the records provided. The medication Medi-Patch .5 Percent-20 Percent #10 with 3 Refills is not medically necessary.