MAXIMUS Federal Services

Case Number:	CM14-0092537		
Date Assigned:	07/25/2014	Date of Injury:	07/15/2004
Decision Date:	06/09/2015	UR Denial Date:	06/12/2014
Priority:	Standard	Application Received:	06/18/2014

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. 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:

This is a 60 year old female patient who sustained an industrial injury on 7/15/2004 due to cumulative trauma. Diagnoses include bilateral upper extremity overuse syndrome and bilateral carpal tunnel syndrome with surgical repair. Per the physician notes dated 4/29/2014, she had ongoing symptoms of bilateral wrists. The physical examination of the bilateral wrists revealed scar, visible CMC joint prominence, full range of motion except right wrist palmar flexion 52 degrees and positive grind sign in both thumbs. The current medications list is not specified in the records provided. She has had bilateral wrists X-rays many years ago and bilateral wrist MRIs in 2011. Prior diagnostic study reports were not specified in the records provided. She was permanent and stationary in 2007. She has undergone left carpal tunnel release in 1/2006 and right carpal tunnel release in 5/2006. She has had physical therapy visits for this injury.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription of Theraproxen 500mg (Theramin 90 and Naproxen 500mg): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic - Medical food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter- Pain (updated 4/30/15) Medical food Theramine.

Decision rationale: Request: 1 Prescription of Theraproxen 500mg (Theramin 90 and Naproxen 500mg) Theraproxen 500mg contains theramine and naproxen. 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 do 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 is 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. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. The 1 Prescription of Theraproxen 500mg (Theramin 90 and Naproxen 500mg) is not medically necessary at that time.

1 X-ray Series of Both Wrists 3 Views: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 267-8.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 268-269.

Decision rationale: Request: 1 X-ray Series of Both Wrists 3 Views, Per the ACOEM's Occupational Medicine Practice Guidelines "For most patients presenting with true hand and wrist problems, special studies are not needed until after a four- to six-week period of conservative care and observation. Most patients improve quickly, provided red flag conditions are ruled out. Exceptions include the following: "In cases of wrist injury, with snuff box (radial-dorsal wrist) tenderness, but minimal other findings, a scaphoid fracture may be present. Initial radiographic films may be obtained but may be negative in the presence of scaphoid fracture." Any indication listed above that would require bilateral wrist X-rays was not specified in the records provided. Evidence of red flag signs was not specified in the records provided. Response to previous conservative therapy including physical therapy visits and pharmaco-therapy is not specified in the records provided. Per the cited guidelines "If symptoms have not resolved in four to six weeks and the patient has joint effusion, serologic studies for Lyme disease and autoimmune diseases may be indicated. Imaging studies to clarify the diagnosis may be warranted if the medical history and physical examination suggest specific disorders." A detailed physical examination of the bilateral wrist suggesting specific disorders was not specified in the records provided. Any snuff box tenderness on exam was not specified in the records provided. Prior wrist MRI reports were not specified in the records provided. The 1 Xray Series of Both Wrists 3 Views is not medically necessary for this patient.