MAXIMUS Federal Services

Case Number:	CM14-0038686		
Date Assigned:	06/27/2014	Date of Injury:	09/22/2010
Decision Date:	08/19/2014	UR Denial Date:	04/01/2014
Priority:	Standard	Application Received:	04/02/2014

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. The expert reviewer is Board Certified Occupational Medicine 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 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/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 46-year-old female who has submitted a claim for right impingement syndrome, right bicipital tenosynovitis, right medial epicondylitis, and right ulnar nerve compression; associated with an industrial injury date of 09/22/2010. The medical records from 2013 to 2014 were reviewed and showed that patient complained of right shoulder, right elbow, and right wrist pain, graded 8/10. Pain is aggravated by repetitive lifting and carrying, and repetitive movements. A physical examination showed tenderness over the right shoulder and right elbow. The ranges of motion of the right shoulder, right elbow, right forearm, and right wrist were limited by pain. Orthopaedic tests of the right shoulder and elbow was positive. Tinel's sign was positive on the right wrist, the deep tendon reflexes were normal, motor testing showed weakness of shoulder abduction and flexion and the sensation was intact. The treatment to date has included medications, acupuncture, physical therapy, chiropractic therapy, intraarticular cortisone injections, and right shoulder surgeries. The utilization review, dated 04/01/2014, denied the requests for Sentra PM, Trepadone, and Theramine because guidelines do not recommend their use; and denied the request for Medrox patches because there was no documented failure of or intolerance to first-line medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra Pm #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - Gamma-amonibutyric acid (GABA).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Medical Food & Sentra PM.

Decision rationale: Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines (ODG) was used instead. According to ODG, Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of Choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for Choline supplementation except for the case of long-term parenteral nutrition or for individuals with Choline deficiency secondary to liver deficiency. Glutamic Acid is used for treatment of hypochlorhydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, there is no documentation of the abovementioned conditions or of nutritional deficiencies to support this request. Therefore, the request for Sentra PM #60 is not medically necessary.

Theramine: 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 Chapter, Medical foods.

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

Decision rationale: Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the ODG was used instead. According to ODG, Theramine is not recommended. It is a medical food that is a proprietary blend of GABA and Choline bitartrate, L-arginine, and L-serine intended for management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Regarding GABA, there is no high quality peer-reviewed literature that suggests that GABA is indicated. Regarding Choline, there is no known medical need for supplementation. Regarding L-Arginine, this medication is not indicated in current references for pain or inflammation. Regarding L-Serine, there is no indication for the use of this product. In this case, patient was prescribed Theramine since at least December 2013. However, guidelines do not support the use of Theramine. There is no discussion concerning need for variance from the guidelines. Therefore, the request for Theramine is not medically necessary.

Trapadone: 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 Chapter, Medical foods.

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

Decision rationale: Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the ODG was used instead. Trepadone is a medical food that is a proprietary blend of L-arginine, L-glutamine, Choline bitartrate, L-serine, and GABA. It is intended for use in the management of joint disorders associated with pain and inflammation. Regarding GABA, there is no high quality peer-reviewed literature that suggests that GABA is indicated; regarding Choline, there is no known medical need for Choline supplementation; regarding L-Arginine, this medication is not indicated in current references for pain or inflammation; and regarding L-Serine, there is no indication for the use of this product. Patient has been on this medication since at least December 2013. However, there is no documentation regarding failure of or intolerance to first-line anti-inflammatory and pain medications in this patient to support the use of this medical food. Moreover, there is no guideline evidence to support the use of Trepadone. Lastly, the present request as submitted failed to specify the number to be dispensed. Therefore, the request for Trepadone was not medically necessary.

Medrox Patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Salicylate Topicals.

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Medrox contains 5% methyl Salicylate, 20% menthol, and 0.0375% capsaicin. The California MTUS states that there are no current indications for a capsaicin formulation of 0.0375%. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl Salicylate, or capsaicin, may in rare instances cause serious burns. Moreover, any compounded product that contains at least one drug that is not recommended is not recommended. In this case, the patient has been using Medrox patches since at least December 2013. Patient has persistent pain despite intake of oral pain medications; hence, Medrox patch was prescribed. However, the guideline does not recommend capsaicin in 0.0375% formulation. Moreover, the present request

as submitted failed to specify the number to be dispensed. Therefore, the request for Medrox patches is not medically necessary.