MAXIMUS Federal Services

Case Number:	CM15-0200991		
Date Assigned:	10/19/2015	Date of Injury:	06/09/2011
Decision Date:	12/08/2015	UR Denial Date:	09/29/2015
Priority:	Standard	Application Received:	10/13/2015

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: California
Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 60 year old male who sustained an industrial injury on 06-09-2011. A review of the medical records indicated that the injured worker is undergoing treatment for cervical sprain and strain, left shoulder impingement and lateral epicondylitis. The injured worker is status post left shoulder surgery on 08-15-2014 (procedure was not noted). According to the treating physician's progress report on 09-011-2015, the injured worker continues to experience constant left shoulder pain rated at 8 out of 10 on the pain scale. Examination demonstrated tenderness to palpation along the subacromial segment joint and along the trapezius muscles with palpable spasms. Range of motion was noted as flexion at 130 degrees, extension at 20 degrees, abduction at 120 degrees, adduction at 20 degrees and internal and external rotation at 60 degrees each. Impingement sign was positive. An official report of a magnetic resonance imaging (MRI) of the cervical spine was included in the review. Prior treatments have included diagnostic testing, surgery, trigger point injections, home exercise program and medications. Current medications were listed as Tramadol, Percocet and Terocin patches. Treatment plan consists of continuing with home exercise program, topical analgesics and the current retrospective request for Sentra AM #90 (DOS: 09-11-2015) and the retrospective request for Theramine #90 (DOS: 09-11-2015). On 09-29-2015 the Utilization Review determined the retrospective requests for Sentra AM #90 (DOS: 09-11-2015 and the retrospective request for Theramine #90 (DOS: 09-11-2015) were not medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Sentra AM #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.nutrientpharmacology.com/sentra_AM.html.

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, under Medical Food.

Decision rationale: The patient presents on 09/11/15 with left shoulder pain rated 8/10. The progress note associated with this request is poorly scanned and illegible in some portions. The patient's date of injury is 06/09/11. Patient is status post unspecified left shoulder surgery on 08/15/14. The request is for RETROSPECTIVE SENTRA AM #90. The RFA was not provided. Physical examination dated 09/11/15 reveals left shoulder range of motion to be 130 degrees on flexion, 20 degrees on extension, 120 degrees on abduction, 20 degrees on adduction, and 60 degrees on internal/external rotation. The provider also notes tenderness to palpation over the subacromial region, paracervical muscles, and trapezius muscles with positive impingement sign noted. The patient is currently prescribed Tramadol, Percocet, and topical compounded creams. Patient's current work status is not provided. Official Disability Guidelines, Pain chapter, under Medical Food has the following: Not recommended for chronic pain... Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain... Choline: Choline is a precursor of acetylcholine. 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. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). In regard to the request for Sentra AM, this patient does not present with diagnosis or symptoms pertinent to this medication. Nutritional supplements such as Sentra AM are sometimes prescribed for cognitive disorders secondary to Choline deficiency. While this patient presents with unresolved chronic pain secondary to shoulder injury and surgical intervention, there are no diagnoses addressing Choline nutritional deficiency, liver disease, or examination findings, which support such a conclusion. The reports provided do not indicate that said supplement will be administered under medical supervision, either. Therefore, this request IS NOT medically necessary.

Retrospective 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, Pain, 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 Chapter, under Medical Food.

Decision rationale: The patient presents on 09/11/15 with left shoulder pain rated 8/10. The progress note associated with this request is poorly scanned and illegible in some portions. The patient's date of injury is 06/09/11. Patient is status post unspecified left shoulder surgery on 08/15/14. The request is for RETROSPECTIVE THERAMINE #90. The RFA was not provided. Physical examination dated 09/11/15 reveals left shoulder range of motion to be 130 degrees on flexion, 20 degrees on extension, 120 degrees on abduction, 20 degrees on adduction, and 60 degrees on internal/external rotation. The provider also notes tenderness to palpation over the subacromial region, paracervical muscles, and trapezius muscles with positive impingement sign noted. The patient is currently prescribed Tramadol, Percocet, and topical compounded creams. Patient's current work status is not provided. Official Disability Guidelines, Pain Chapter, under Medical Food states: Not recommended for the treatment of chronic pain... Theramine is a medical food that contains 5-hydroxytrytophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors. (Micromedex, 2015) See Medical food. Under this entry discussions of the various components of this product are given. The entries for 5-hydorxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA are given and all indicate there is no role for these supplements as treatment for chronic pain. In regard to the request for Theramine, this medication is not supported by guidelines for chronic pain. While the requesting physician feels as though this medication is an appropriate therapy for this patient's chronic pain condition, official disability guidelines do not support its use owing to a lack of high-quality applicable studies demonstrating efficacy for chronic pain conditions. There is no indication that this medication is being utilized/administered under medical supervision, either. Therefore, the request IS NOT medically necessary.