

Case Number:	CM15-0133287		
Date Assigned:	07/21/2015	Date of Injury:	08/24/2014
Decision Date:	08/26/2015	UR Denial Date:	06/17/2015
Priority:	Standard	Application Received:	07/09/2015

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, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 was a 52 year old female, who sustained an industrial injury, August 24, 2014. The injury was sustained when the injured worker was climbing up a flight of stairs, holding the rail with the right hand and arm, at which time the injured worker tripped on the stairs and fell. The injured worker landed at the bottom of the stairs on her stomach. The injured worker had a complaint of right shoulder pain. The injured worker previously received the following treatments Norco, Trepadone, App Trim and Theramine, acupuncture, 12 sessions of physical therapy and right shoulder MRI was inconclusive. The injured worker was diagnosed with depression and abnormal sleep right shoulder internal derangement, right shoulder pain and possible adhesive capsulitis. According to progress note of April 15, 2015, the injured worker's chief complaint was right shoulder pain. The pain was rated at 7 out of 10. The pain increased with repetitive activity of the right arm and hand, over the head reaching or reaching behind. The Theramine helped with the fibromyalgia, neuropathic pain and inflammatory pain. Trepadone helped with pain and inflammation associated with joint disorder. The pain level varied throughout the day depending on activity. The injured worker was experiencing insomnia and chronic pain. The injured worker was unable to sleep on the right side. The injured worker was having trouble with dressing bathing, brushing hair cleaning and grocery shopping. The physical exam noted decreased range of motion of the right upper extremity with flexion of 100 degrees, extension of 25 degrees, abduction of 90 degrees, adduction of 30 degrees, internal rotation of 50 degrees and external rotation of 50 degrees. The impingement sign was positive on the right. The treatment plan included prescriptions for App trim, Theramine and Trepadone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 5/325mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 91.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding ongoing management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the 4 A's (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of norco nor any documentation addressing the '4 A's' domains, which is a recommended practice for the ongoing management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. It is noted that UDS was performed in 9/2014, however, results were not available for review. CURES report was not reviewed. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

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.

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.

Decision rationale: The MTUS is silent on the topic of medical food. With regard to the treatment of chronic pain, the ODG guideline says this about theramine: 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." Theramine is not recommended by the ODG and thus the request is not medically necessary.

Trepadone #120: 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.

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), Trepadone.

Decision rationale: The MTUS is silent on the use of Trepadone, per the ODG guidelines: Not recommended. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. As Trepadone is not recommended, the request is not medically necessary.

Appttrim #120: 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.

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

Decision rationale: Per internet search, Appttrim is a medical food formulated by practicing physicians to meet the nutritional requirements of obese patients and to be used for specific dietary management of obesity. The MTUS is silent on the topic of medical food. Per the ODG guidelines with regard to medical food: 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 internally 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. As Appttrim is not recommended, the request is not medically necessary.