

Case Number:	CM13-0036864		
Date Assigned:	12/18/2013	Date of Injury:	03/25/2013
Decision Date:	02/21/2014	UR Denial Date:	09/26/2013
Priority:	Standard	Application Received:	10/21/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management has a subspecialty in Disability Evaluation and is licensed to practice in California, Maryland, Florida and District of Columbia. 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 physician 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:

This patient reported a date of injury of 3/25/2013. He reported experiencing pain isolated to the area under the deltoid. He has had an MRI completed on 7/08/13 that demonstrates an extensive SLAP IV lesion of the right glenoid labrum, extending from the 9 to 1 o'clock position to the biceps anchor. This is involving the biceps tendon, which is nearly completely disrupted. Mild tendinopathy of the supraspinatus. He is status post right shoulder arthroscopy. The 9/10/13 progress report indicates persistent right shoulder pain. Physical exam demonstrates severe pain preventing physical exam. The patient has a noticeable Popeye deformity of the biceps. The Treatment to date has included physical therapy and medication. The request is for 1) Game Ready 28 day rental, 2) Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Game Ready 28 day rental: Upheld

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

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

Decision rationale: CA MTUS does not specifically address this issue. ODG states that continuous-flow cryotherapy is recommended as an option after surgery, but not for nonsurgical treatment. Postoperative use generally may be up to 7 days, including home use. In the postoperative setting, continuous-flow cryotherapy units have been proven to decrease pain, inflammation, swelling, and narcotic usage; however, the effect on more frequently treated acute injuries (eg, muscle strains and contusions) has not been fully evaluated. The Game Ready system combines Continuous-flow cryotherapy with the use of vasocompression. While there are studies on Continuous-flow cryotherapy, there are no published high quality studies on the Game Ready device or any other combined system. However, in a recent yet-to-be-published RCT, patients treated with compressive cryotherapy after ACL reconstruction had better pain relief and less dependence on narcotic use than patients treated with cryotherapy alone. (Waterman, 2011). The guideline recommended for use of Game Ready cold unit postoperatively for up to 7 days, including home use. Therefore the request Game Ready 28 day rental 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 (ODG), Theramine

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

Decision rationale: CA MTUS (Effective July 18, 2014) is mute on Theramine. According to Daily Med, Primary Ingredients of Theramine consists of a proprietary formulation of Gamma Aminobutyric Acid, Choline Bitartrate, Whey Protein Hydrolysate, L-Arginine, L-Histidine, L-Glutamine, Theobromine, Griffonia See, Grape Seed, L-Serine, and Cinnamon in specific proportions. These ingredients fall into the classification of Generally Recognized as Safe (GRAS) as defined by the Food and Drug Administration (FDA) (Sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act). A GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use. In the medical report date 9/10/2013, the treating physician stated "Theramine stimulates production of neurotransmitters such as serotonin, GABA, Norepinephrine, nitric oxide and acetylcholine. It provides the nutrients that have been depleted due to certain disease states or as a result of certain drug side effects. If the timing and secretion of the neurotransmitters are effectively modulated, acute and chronic pain disorders are more effectively managed. It is that nutritional deficiency that contributes to the patient's chronic pain, which has causal relationship with the Industrial injury". However there is no laboratory report supporting the fact that this patient has any nutritional deficiency that will require a diet supplement like Theramine. According to FDA/ODG recommendation, medical foods 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, are established by medical evaluation. There is no documentation of any specific condition for which distinctive nutritional requirements based on recognized scientific principles, are established by medical evaluation that will require a Theramine supplement in this patient. Therefore the request for Theramine is not medically necessary.