

Case Number:	CM14-0116394		
Date Assigned:	08/06/2014	Date of Injury:	06/27/2013
Decision Date:	10/01/2014	UR Denial Date:	07/18/2014
Priority:	Standard	Application Received:	07/24/2014

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 in Physical Medicine and Rehabilitation, has a subspecialty in Pain 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 48 year old female who sustained an industrial injury on 6/27/2013. She underwent right shoulder arthroscopic RCR and SAD on 5/9/2014. She presented for a follow up for her right shoulder on 5/19/2014. Pain is rated 7-8/10 with medications. Prior to surgery, pain was 9/10 on VAS. She is using ibuprofen 600mg three time per day for pain, and also uses Tramadol ER, which feels it is not helping with her postoperative pain. Physical examination reveals normal muscle tone and no skin abnormalities observed in the extremities. Diagnosis is shoulder joint pain. She is prescribed hydrocodone 5/325 #30 and protonix. Tramadol ER is discontinued. The surgical incisions are healing well. She is TTD.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theraprogen # 90 retro 6/19/14: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 22, 51. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine; Medical Food Other Medical Treatment Guideline or Medical Evidence:

http://nutrientpharmacology.com/PDFs/copacks/Theramine-Theraprogen90_Ibuprofen600-co_pack.pdf

Decision rationale: ODG: 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. Theraprogen is a convenience pack that contains Ibuprofen and Theramine. The guidelines recommend NSAIDS, such as ibuprofen, as an option for short-term symptomatic relief. According to the 5/19/2014 report, the patient's medication regimen already included Ibuprofen 600mg, as well as 325mg APAP from the Norco. According to the documentation, the patient was dispensed Theraprogen #90 on 6/19/2014. As detailed in the Official Disability Guidelines, Theramine is not recommended. Theraprogen contains Theramine, which is not recommended according to the evidence-based guidelines. Therefore the medical necessity of retro Theraprogen #90 6/19/2014 is not established. The request is not medically necessary and appropriate.