

<b>Case Number:</b>	CM14-0004925		
<b>Date Assigned:</b>	01/24/2014	<b>Date of Injury:</b>	12/09/2012
<b>Decision Date:</b>	05/29/2014	<b>UR Denial Date:</b>	12/20/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/14/2014

### 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 & Rehabilitation has a subspecialty in Neuromuscular Medicine and is licensed to practice in Maryland. 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 reported a date of work injury of 12/9/12 to her right shoulder deemed secondary to cumulative trauma. The patient had conservative treatment for the shoulder but eventually underwent a right shoulder arthroscopic repair of a subacromial decompression on 9/17/13 for impingement syndrome of the right shoulder. There is a request for the medical necessity of Theraprogen-800mg. There is a 10/23/13 office visit document that states that the patient is status post-operative right shoulder arthroscopic subacromial decompression, 09-17-2013. She indicates the CPM Machine is helping. She feels she is improving following surgery. She had a hot/cold machine which was also beneficial. On physical examination, there are well healed surgical portal scars on the right shoulder. A partial suture was removed from one of the portal scars. There is slight post-operative swelling about the shoulder with slight tenderness to palpation. She has decreased range of motion, but she is able to flex and abduct the shoulder to Final Determination Letter for IMR Case Number CM14-0004925 3 about 115 degrees. The treatment plan is to continue post op therapies as well as compounds are being dispensed at this time for pain relief.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**THERAPROFEN - 800:** 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 NSAIDS Page(s): 67. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain – Theramine.

**Decision rationale:** Therapfen 800 contains Ibuprofen 800mg and Theramine which is considered a medical food. The ODG states that Theramine is not recommended. The MTUS states that NSAIDs can be used at the lowest dose for the shortest period in patients with moderate to severe pain. The documentation indicates that patient has been on long term NSAIDs without significant functional improvement. The ODG states that Theramine® is a medical food 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. The ODG states in regards to Gamma-aminobutyric acid (GABA) that "There is no high quality peer-reviewed literature that suggests that GABA is indicated". In regards to Choline, the ODG states that "There is no known medical need for choline supplementation". In regards to L-Arginine, the ODG states that "This medication is not indicated in current references for pain or inflammation"; & for L-Serine, guidelines state that, "There is no indication for the use of this product." The ODG states that until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The documentation does not indicate a nutritional deficiency of why this patient is unable to take Ibuprofen alone. Furthermore, the documentation indicates that the patient has been on chronic NSAIDs without functional improvement. In the absence of any nutritional deficiency, history of chronic NSAID use and the ODG stating that there are no high quality studies of the ingredients in Theramine which is contained in Therapfen. The request for Therapfen 800 is not medically necessary and appropriate.