

<b>Case Number:</b>	CM13-0009326		
<b>Date Assigned:</b>	11/08/2013	<b>Date of Injury:</b>	12/15/2005
<b>Decision Date:</b>	02/28/2015	<b>UR Denial Date:</b>	07/29/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/12/2013

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & Gen Prev Med

### 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 is a 64 year old male who sustained a work related injury on 12/15/2005. The mechanism of injury has not been provided with the clinical documentation submitted for review. Per the Primary Treating Physician's Progress Report dated 6/27/2013, the injured worker reported right shoulder pain. He reported an incident during physical therapy in which he felt a sharp pain during a forward flexion stretch that has not improved. He is status-post right shoulder rotator cuff repair with biceps tenodesis dated 04/01/2013. Objective physical examination of the cervical spine reveals forward flexion two inches chin to chest, extension 30 degrees, and rotation to the right and left 30 degrees. Deep tendon reflexes of the upper extremities are 2+bilaterally. Grip strength of the upper extremities is from 3- to 4/5. He has normal sensation to touch of the upper extremities. Cervical exam reveals a positive Waddell's sign. Right shoulder flexion is 65 degrees, abduction 70 degrees, external rotation 50 degrees and internal rotation 20 degrees. Lumbar spine exam reveals forward flexion two feet from hands to the floor, extension 10 degrees, lateral bending to the left and right 20 degrees. Straight leg raise test is positive bilaterally. Deep tendon reflexes of the lower extremities at the right L4 is 3+, left L4 is 2+, and bilateral S1 is 2+. Diagnoses included cervicgia, lumbago, sciatica, bilateral shoulder pain, bilateral rotator cuff tendinosis, and bilateral impingement. The plan of care included magnetic resonance imaging (MRI) of the right shoulder and medication management. Work status is temporarily totally disabled. On 7/08/2013 a request was made for an MRI of the right shoulder, Norco 10/325 #60, Soma 350mg #30 x 3 and Theramine #90 x 5. On 7/26/2013, Utilization

Review non-certified the prescription of Theramine #90 and modified the prescription for Norco 10/325 #60, based on lack of medical necessity. The CA MTUS ACOEM Guidelines were cited

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Norco 10/325mg #60:** 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 Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Opioids, Pain

**Decision rationale:** ODG does not recommend the use of opioids for neck and low back pain except for short use for severe cases, not to exceed 2 weeks. The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. While the treating physician documents a shoulder pain flare up, the treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the question for Norco 325/10mg #60 is not medically necessary.

**Theramine #90:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (Chronic), Theramine and medical food

**Decision rationale:** ODG states that a medical food 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. ODG comments on Theramine directly, not recommended. Theramine is a medical food from Physician Therapeutics, Los Angeles, CA, 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. The ODG guidelines do not support the use of Theramine. As such the request for Theramine #90 is not medically necessary.