

<b>Case Number:</b>	CM13-0069239		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	12/07/2010
<b>Decision Date:</b>	05/22/2014	<b>UR Denial Date:</b>	12/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/20/2013

### 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. The expert reviewer is Board Certified in Anesthesiology, Pain Medicine, and is licensed to practice in Florida. 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 injured worker is a 48-year-old female who reported an injury on 12/07/2010. The mechanism of injury was not provided in the medical records. The clinical note dated 11/14/2013 reported the injured worker was having neck and bilateral shoulder blade pain. The injured worker also had limited range of motion to cervical spine, with flexion to 20 degrees and extension to 20 degrees. The injured worker had mild tenderness and spasm in the right and left paravertebral and trapezius musculature. The provider recommended theramine as a nutritional management of ongoing severe chronic pain. The provider also recommended terocin patches and gabapentin. The injured worker had diagnoses including cervicalgia (723.1) and cervical degenerative disc disease and mild spondylosis C5-C6, C6-7 (722.4). The request for authorization for review was submitted 12/20/2013

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TEROCIN PATCHES #10:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** The injured worker has ongoing cervical neck pain radiating into both trapezius and bilateral shoulder blade region. MRI (magnetic resonance imaging) scan revealed minimal annular bulging at C5-6 and C6-7 with mild spondylosis. Terocin patches are a combination of lidocaine 4% and menthol 4 %. According to the CA MTUS, the use of compounded agents requires knowledge of specific analgesic effect of each agent. There is little to no research to support the use of many compound agents. Topical analgesics work locally underneath the skin where they are applied. Furthermore, topical lidocaine, in the formulation of a dermal patch (Lidoderm®) has been designated for orphan status by the Food and Drug Administration (FDA) for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. There is a lack of evidence of the efficacy of the terocin patches as evidenced by decreased pain and significant objective functional improvement. Additionally, the guidelines note Lidoderm has been approved for orphan status and no other topical forms of lidocaine are recommended. As such, the request for terocin patches # 10 is non-certified

**THERAMINE #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Overview of Dietary Supplements. FDA Center for Food Safety and Applied Nutrition. Food and Drug Administration. <http://www.cfsan.fda.gov/~dms/dsoview.html#regulate>; Ibid, Curatolo, M. & Bogduk, N. (2001). Pharmacologic pain treatment of musculoskeletal disorders:

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

**Decision rationale:** According to the Official Disability Guidelines (ODG), Theramine is not recommended. The ODG guidelines note 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. There is no known need for choline supplementation. L-Arginine is not indicated in the current references for pain or inflammation. There is no indication for the use of L-Serine. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. There is a lack of evidence within the provided documentation indicating the injured worker had any dietary insufficiencies which would indicate the injured workers need for theramine. There is a lack of evidence of the efficacy of theramine as evidenced by significant objective functional improvement. Additionally, the guidelines note Theramine is not recommended. As such, the request for theramine # 90 is non-certified.