

<b>Case Number:</b>	CM15-0113833		
<b>Date Assigned:</b>	06/22/2015	<b>Date of Injury:</b>	01/30/2002
<b>Decision Date:</b>	07/22/2015	<b>UR Denial Date:</b>	06/04/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/12/2015

### 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: New Jersey, New York  
Certification(s)/Specialty: Family Practice

### 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 61 year old male, who sustained an industrial injury on 1/30/2002. The current diagnoses are lumbosacral radiculopathy and depressive disorder. According to the progress report dated 5/14/2015, the injured worker complains of pain in the bilateral L5 and S1 distribution. The pain is rated 2-3/10 on a subjective pain scale. The physical examination of the lumbar spine reveals positive bilateral facet maneuvers L4-5 and L5-S1, positive straight leg raise test on the right and absent ankle reflexes bilaterally. Treatment to date has included medication management, MRI studies, and chiropractic. The plan of care includes prescriptions for Trepadone, Theramine, and Terocin lotion.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Trepadone:** 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), Trepadone.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food, FDA section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Trepadone is a medical food marketed for joint disorders to treat pain and inflammation. The FDA defines medical food in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "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." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Trepadone does not meet the requirement for medical food as stated by the FDA. There is no documented nutritional deficiency for which a medical food is required. There was also no objective documentation of improvement in functional capacity. Therefore, Trepadone 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Honey & Cinnamon Page(s): 51. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food, FDA section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Theramine is a medical food used in the treatment of pain syndromes. Its ingredients include neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). The FDA defines medical food in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered internally 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." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Theramine does not meet the requirement for medical food as stated by the FDA. There is no documented nutritional deficiency for which a medical food is required. One specific ingredient, cinnamon, is not recommended for chronic pain. When one component of a treatment is not recommended,

then the whole treatment is not recommended. There was also no objective documentation of improvement in functional capacity. Therefore, Theramine is not medically necessary.

**Terocin lotion:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm, topical analgesics Page(s): 56-57, 111-112.

**Decision rationale:** The request is not medically necessary. According to MTUS guidelines, Lidoderm is not first line treatment and is only FDA approved for post-herpetic neuralgia. More research is needed to recommend it for chronic neuropathic pain other than post-herpetic neuralgia. There are also no guidelines for the use of menthol with the patient's spine complaints. Topical analgesics are used when patient is unable to tolerate oral medications which is not documented in the chart provided. Therefore, the request is considered not medically necessary.