

<b>Case Number:</b>	CM14-0064964		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	05/16/2009
<b>Decision Date:</b>	07/03/2015	<b>UR Denial Date:</b>	04/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/07/2014

### 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. 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: Texas, California  
 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 41-year-old male, who sustained an industrial injury on May 16, 2009. He reported severe burns to over seventy percent of the body surface after a motor vehicle accident. The injured worker was diagnosed as having status post motor vehicle accident not involving another motor vehicle with subsequent explosion and fire, 70-79% body surface burn, chronic pain syndrome, prescription narcotic dependence, insomnia, anxiety and depression. Treatment to date has included medical treatment of the burn wounds, skin treatments, conservative therapies, medications and work restrictions. Currently, the injured worker complains of continued skin irritations and burning sensations on the effected body surface. He required pain medications for pain control and to remain functional. The injured worker reported an industrial injury in 2009, after a tanker truck he was driving exploded, resulting in the above noted pain. He was treated conservatively without complete resolution of the pain. Evaluation on July 21, 2014, revealed continued pain as noted with associated symptoms. Medications were requested. The patient has had urine drug screen test on 6/26/13 and on 8/12/14 that was positive for opioid. The medication list includes Opana, Lyrica, Trepadone, Tylenol and Percura.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**GABAdone #60:** 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), Pain (Chronic).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Treatment Index, 8th Edition (web),ODG Pain (updated 06/15/15) GABAdone Medical food.

**Decision rationale:** Theramine is a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-Histidine, choline bitartrate, 5-Hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenol antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The ACOEM and CA MTUS do not address these medications. The contents of these medical food products are not recommended by the Official Disability Guidelines. According to the guidelines, 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. To be considered the product must, at a minimum, must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The response to other pharmacological measures for treatment of pain was not specified in the records provided. There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. Therefore, there is no medical necessity for any medication containing these food supplements. Any evidence of nutritional deficiency of the contents of this product was not specified in the records provided. Therefore, the request is not medically necessary.

**Theramine #120:** 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), Pain (Chronic).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Index, 8th Edition (web), Chapter- Pain (updated 06/15/15) Medical food.

**Decision rationale:** Theramine is a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-Histidine, choline bitartrate, 5-Hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenol antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia,

neuropathic pain, and inflammatory pain. The ACOEM and CA MTUS do not address these medications. The contents of these medical food products are not recommended by the Official Disability Guidelines. According to the guidelines, 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. To be considered the product must, at a minimum, must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The response to other pharmacological measures for treatment of pain was not specified in the records provided. There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. Therefore, there is no medical necessity for any medication containing these food supplements. Any evidence of nutritional deficiency of the contents of this product was not specified in the records provided. Therefore, the request is not medically necessary.

**Trepadone #120:** 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), Pain (Chronic).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Index, 8th Edition (web), Chapter- Pain (updated 06/15/15) Medical food.

**Decision rationale:** Trepadone is a medical food from [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gamma-aminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. The ACOEM and CA MTUS do not address these medications. The contents of these medical food products are not recommended by the Official Disability Guidelines. According to guidelines, 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. To be considered the product must, at a minimum, be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. Any evidence of nutritional deficiency of the contents of this product was not specified in the records provided. There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. Therefore, there is no medical necessity for any medication containing these food supplements. The response to other pharmacological measures for treatment of pain was not specified in the records provided. Therefore, the request is not medically necessary.

**MS Contin 60mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 76-80.

**Decision rationale:** Norco contains Hydrocodone with APAP, which is an opioid analgesic in combination with acetaminophen. According to CA MTUS guidelines, a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. The records provided do not specify that the patient has set goals regarding the use of opioid analgesic. A treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: the lowest possible dose should be prescribed to improve pain and function; continuing review of the overall situation with regard to nonopioid means of pain control; ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; and consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. The records provided do not provide a documentation of response in regard to pain control and functional improvement to opioid analgesic for this patient. The continued review of overall situation with regard to nonopioid means of pain control is not documented in the records provided. The level of pain control with lower potency opioids like tramadol and other non-opioid medications, without the use of MS Contin, was not specified in the records provided. As recommended by MTUS a documentation of pain relief, functional status, appropriate medication use, and side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. A recent urine drug screen report was not specified in the records provided. Whether improvement in pain translated into objective functional improvement, including ability to work is not specified in the records provided. With this, it is deemed that, this patient does not meet criteria for ongoing continued use of opioids analgesic. Therefore, the request is not medically necessary.