

Case Number:	CM15-0012666		
Date Assigned:	01/30/2015	Date of Injury:	07/26/2010
Decision Date:	05/07/2015	UR Denial Date:	12/26/2014
Priority:	Standard	Application Received:	01/22/2015

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 York

Certification(s)/Specialty: Pediatrics, Internal Medicine

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 58 year old female, who sustained an industrial injury on July 26, 2010. She has reported lower back pain. The diagnoses have included lumbar radiculopathy and post-traumatic stress disorder. Treatment to date has included MRI, work/activity modifications, physical therapy, and medications including analgesic, anti-anxiety, non-steroidal anti-inflammatory, topical compound cream, and muscle relaxant. On October 18, 2014, the treating physician noted intermittent lower back pain radiating to the right buttock, hip, and leg, which had slightly improved back pain since prior visit. There was numbness and tingling in the right leg and foot. In addition, the injured worker had bowel dysfunction. Currently, the injured worker was using a non-steroidal anti-inflammatory medication. The physical exam revealed moderately decreased lumbar range of motion, positive straight leg raise, normal motor exam, normal reflexes, and diminished sensation to light touch in the lumbar 5 and sacral 1 nerve root distributions. On January 22, 2015, the injured worker submitted an application for IMR for review of prescriptions for Terocin pain patches box #20, Methoderm gel 120gm, Theramine #90, Trepadone #90, Sentra AM #60, Sentra PM #60, and Gabadone #60. The Terocin was non-certified based on lack of evidence of localized peripheral neuropathic pain and failure of first-line therapy. The Methoderm gel was non-certified based on lack of documentation of approved conditions for treatment with topical analgesics, and unclear rationale for the use of topical medications rather than the (Food and Drug Administration) approved oral forms. The Theramine, Trepadone, Sentra AM, Sentra PM, and Gabadone were non-certified based on the lack of consistent evidenced-based support for the use of these medical foods. The California

Medical Treatment Utilization Schedule (MTUS), Chronic Pain Medical Treatment Guidelines and Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin pain patch box #20: 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: MTUS guidelines state that lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy. The documentation in the case file does not indicate that the Injured Worker tried any other medications without success. Even though menthol is approved for topical use this cannot be approved due to other components not being medically necessary. This request is not medically appropriate and reasonable at this time.

Menthoderm gel 120gm: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Salicylates.

Decision rationale: ODG guidelines recommended topical salicylates as an option. Menthoderm is an over the counter topical gel solution. The blend of ancient natural remedies Methyl Salicylate and Menthol. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in acute and chronic pain, but especially acute pain. There is no clear indication in the documentation that the Menthoderm is to be utilized for, without a clear indication or site of pain the request is not medically necessary and appropriate.

Theramine #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Medical Food and Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

Decision rationale: MTUS guidelines do not comment on the use of Theramine. ODG states that Theramine is not recommended for the treatment of chronic pain. See Medical food. Under this entry discussions of the various components of this product are given. The entries for 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA are given and all indicate there is no role for these supplements as treatment for chronic pain. This request is not medically necessary and appropriate at this time.

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, Pain Chapter, Medical Food and Trepadone.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

Decision rationale: MTUS guidelines do not comment on the use of Trepadone. ODG states that Trepadone is not recommended. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. There is insufficient evidence to support use for osteoarthritis or for neuropathic pain. This request is not medically necessary and appropriate at this time.

Sentra AM #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, Pain Chapter, Medical Food and Sentra AM.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

Decision rationale: MTUS guidelines do not comment on the use of Sentra. ODG states that Sentra is not recommended. Sentra AM is a medical food from [REDACTED] intended for use in management of fatigue and cognitive disorders. It is a proprietary blend of Choline Bitartrate, Cocoa Extract, L-Glutamic Acid, Acetyl L-Carnitine, Dextrose, Ginkgo Biloba, and Hawthorn Berry. See Medical food, Choline & Glutamic Acid. This request is not medically necessary and appropriate at this time.

Sentra PM #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, Pain Chapter, Medical Food and Sentra PM.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

Decision rationale: MTUS guidelines do not comment on the use of Sentra. ODG states that Sentra is not recommended. Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of neurotransmitter precursors (choline bitartrate, glutamate, and 5-hydroxytryptophan); polyphenolic antioxidants (hawthorn berry, cocoa); an amino acid uptake stimulator (gingko biloba); activators of amino acid utilization (acetyl-L-carnitine, glutamate, cocoa powder); and an adenosine antagonist (cocoa powder). Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. This is a precursor of gamma-aminobutyric acid (GABA). This supplement is used for treatment of gastric hydrochloric acid deficiency. This is the intermediate metabolite between biosynthesis of L-tryptophan to serotonin. In alternative medicine it has been used for insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders (postulated to inhibit inflammation). Current peer-reviewed evidence is inconclusive to support these claims. This request is not medically necessary and appropriate.

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, Pain Chapter, Medical Food and GABA done.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

Decision rationale: MTUS guidelines do not comment on the use of Sentra. ODG states that GABA done is not recommended. GABA done is a Medical food from [REDACTED] that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. This request is not medically necessary and appropriate.