

Case Number:	CM14-0133198		
Date Assigned:	08/22/2014	Date of Injury:	05/23/2014
Decision Date:	10/15/2014	UR Denial Date:	08/08/2014
Priority:	Standard	Application Received:	08/20/2014

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. The expert reviewer is Board Certified in Emergency Medicine and is licensed to practice in California. 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:

This claimant reported injury on 5/23/2014. No specific mechanism of injury was described except a note mentioning a burn to the right forearm. Among the records was a "Doctor's First Report" that was not legible. The injured worker has diagnoses of right forearm burn, radiculopathy of the right hand, and insomnia. The most recent medical report available for review was 7/31/14. However, the last progress note with a physical exam is from 7/23/14. That note mentions an injury (burn to the right forearm) that occurred at the documented date of injury. The pain has reportedly healed but has some persistent pain radiating down hand. The patient also complained of right hand numbness during that visit. The exam reveals a small healing burn to the right forearm, approximately 0.5% total body surface area. There is diffuse tenderness to forearm. There is no documentation included as to why these products and medications were prescribed. A note from 7/31/14 involves an assessment for obstructive sleep apnea. That note is not related to this review. A Urine Drug Screen dated 6/18/14 was appropriate. No advance imaging or electrodiagnostic reports were provided for review. Medications include Bacitracin, Nabumetone, Acetaminophen and Ultracet. A prior UR on 8/8/14 recommended non-certification of requests for Sentra #60 (1 bottle), Theramine #90 (2bottles), Ketoprofen/Cyclobenzaprine/Lidocaine 10/3/5% #120g, and Flurbiprofen/Capsaicin/Camphor 10/0.025/2% #120g.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra #60, 1 Bottle: 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, Updated 6/10/14

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 Foods

Decision rationale: Sentra PM is an herbal supplement marketed as a "medical food." It contains Choline Bitartrate, Glutamic Acid, 5-hydroxytryptophan, Acetyl L-Carnitine, Ginkgo Biloba, Griffonia Extract (5HTP 95%), Hawthorn Berry and Cocoa (from the company's website http://tmedpharma.com/docs/monographs-10-09/Sentra_PM_Monograph_v_Final_10-15-2009.pdf). It is marketed as a sleep aid for people with "nutritional deficiencies associated with sleep disorders." This patient's doctor has prescribed it for sleep management. The ODG indicates a medical food is defined as "a food which is formulated to be consumed or internally [sic] 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 reviews the evidence for each component of Sentra PM for insomnia and concludes that all components have little to no evidence for use in insomnia except for some poor-quality evidence of insomnia improvement with the 5-hydroxytryptophan. Documentation states this injured worker has sleep problems, but there are no details as to the severity of the sleep problem or any significant deficiencies or disability resulting from it. There is no documentation of other attempted treatments for the sleep problem. The patient has no documented nutritional deficiency causing insomnia. Documentation reports that the injured worker's insomnia may be due to sleep apnea and obesity; therefore a "medical food" is not indicated, since there is no nutritional deficiency or documented nutritional special requirements. As such, Sentra PM is not medically necessary.

Theramine #90, 2 Bottles: 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, Updated 07/10/2014

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

Decision rationale: Theramine is a brand name product, being sold by [REDACTED], which contains multiple non-prescription generic substances including "amino acids and polyphenol ingredients," claimed by its manufacturer to aid in various "inflammatory conditions" and pains. There is only marketing information available online. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supportive good-quality studies on the efficacy of this product. The studies often quoted are poorly designed studies.

There are no corresponding sections in ACOEM or MTUS concerning these substances. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally [sic] 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 reviewed each individual component in Theramine and found no evidence to support its use and does not recommend the use of Theramine. This patient has no documented nutritional deficiency causing pain. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Theramine is a non-medicinal substance, with no supporting evidence, with unknown efficacy or safety profile. It is not medically necessary.

Ketoprofen 10%/Cyclobenzaprine 3%/Lidocaine 5% 120gm: 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: As per MTUS guidelines, "Any compounded product that contains a drug or drug class that is not recommended is not recommended." Ketoprofen is not FDA approved for topical applications. Another topical NSAID, Flurbiprofen, was also requested. Duplicated topical NSAIDs (non-steroidal anti-inflammatory drugs) can lead to toxicity, and use of a non-FDA approved application of a medication when there are multiple other topical NSAIDs is not medically necessary. Cyclobenzaprine is not recommended for topical application. Lidocaine is only recommended for neuropathic pain. There is no documentation provided on where this is to be used. There is no proper exam consistent with neuropathic pain, so Lidocaine is not recommended. This compound has multiple non-recommended components and is, therefore, not recommended as medically necessary.

Flurbiprofen 10%/Capsaicin 0.025%/Camphor 2% 120gm: 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: As per MTUS guidelines, "Any compounded product that contains a drug or drug class that is no recommended is not recommended." Flurbiprofen has been shown to be superior to placebo. It should not be used long term. It may be useful. However, this product was requested alongside Ketoprofen, another NSAID, leading to increased risk of toxicity. Flurbiprofen is not recommended, since the provider has not documented proper awareness or monitoring of toxicity. Regarding Capsaicin, data shows efficacy in muscular-skeletal pain, and it may be considered if conventional therapy is ineffective. There is no documentation of prior treatment failure or a successful trial of capsaicin. It is not recommended. Camphor is

considered a non-active filler that may have some topical soothing properties. The active ingredients are not recommended; therefore this compounded ointment is not medically necessary.