

Case Number:	CM14-0123971		
Date Assigned:	09/22/2014	Date of Injury:	05/10/2012
Decision Date:	10/21/2014	UR Denial Date:	07/07/2014
Priority:	Standard	Application Received:	08/06/2014

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 Internal Medicine & Emergency 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:

This patient is a 56 year-old with a date of injury of 05/10/12. A progress report associated with the request for services, dated 05/05/14, identified subjective complaints of bilateral wrist and shoulder pain as well as left knee pain. Objective findings included decreased range of motion of the shoulders, wrists, and knee. Phalen's sign was positive bilaterally. There was decreased sensation in the C6-8 dermatomes. Diagnoses included (paraphrased) bilateral shoulder sprain/strain; bilateral carpal tunnel syndrome, internal derangement of the left knee; and anxiety. Treatment had included oral and topical analgesics. Use of the topicals increased sleep, decreased pain, and increased activity level. A Utilization Review determination was rendered on 07/07/14 recommending non-certification of "Menthoderm gel #240; Xolindo 2% cream; Theramine #90; Sentra AM #60; Gabadone #60; and Sentra PM #60".

IMR ISSUES, DECISIONS AND RATIONALES

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

Menthoderm gel #240: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals; Topical Analgesics Page(s): 105, 111-113. Decision based on Non-MTUS Citation

Official Disability Guidelines (ODG) Pain; Low Back: Topical Analgesics; Salicylate Topicals; Biofreeze Cryotherapy Gel

Decision rationale: Methoderm is a combination topical consisting of methyl Salicylate and menthol. The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Methyl Salicylate is a non-steroidal anti-inflammatory being used as a topical analgesic. The Chronic Pain Guidelines do recommend topical Salicylate as being significantly better than placebo in chronic pain. In osteoarthritis, Salicylate are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical Salicylate as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither Salicylate nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Menthol is a topical form of cooling. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the neck are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute low back pain. There is no recommendation related to the use of menthol for chronic pain. The non-certification was based upon lack of documentation that oral therapy was ineffective. In this case, there is documentation of chronic pain not completely responsive to other therapies. The use of topicals decreases the need for oral therapy, and do provide some functional improvement. The topical ingredients are recommended at least for acute pain and a study found significant pain reduction after each week of treatment. Therefore, there is documented medical necessity for Methoderm cream. The request is medically necessary.

Xolindo 2% cream: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Decision rationale: Xolindo consists of Lidocaine cream, a topical anesthetic. The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that Lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The Guidelines state: "Any compounded product that contains at least one drug (or drug class) that is not

recommended is not recommended." Therefore, in this case, there is no demonstrated medical necessity for Lidocaine with this type of formulation. Likewise, there is no documentation of the failure of conventional therapy or documented functional improvement for the medical necessity of Xolindo. The request is not medically necessary.

Theramine #90: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC) Pain Procedure Summary, updated 05/15/2014

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 Foods

Decision rationale: Theramine is a nutritional supplement containing the active ingredients: choline bitartate; L-glutamine; L-arginine; L-histidine, L-serine, GABA; and 5-hydroxytryptophan as well as cinnamon and a variety of herbals. It is advertised as a medical food for chronic back pain. The Medical treatment Utilization Schedule (MTUS) does not address Theramine. The Official Disability Guidelines (ODG) state that medical foods are recommended for specific dietary management of a disease for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Specifically, it states that Theramine is not recommended. Choline is only recommended for replacement. There is inconclusive evidence that the product is indicated for memory, seizures, or transient ischemic attacks. Glutamate is used for hypochlorhydria and achlorhydria. 5-hydroxytryptophan is possibly effective for anxiety disorders, depression, and fibromyalgia. It has been linked to a contaminant that causes eosinophilia-myalgia syndrome. GABA is indicated for epilepsy, spasticity, and tardive dyskinesia. There is no high quality literature that GABA is indicated for treatment of insomnia. There is no indication for the use of L-serine in numerous references (Micromedex, Clinical Pharmacology, or AltMedDex). L-arginine is not indicated in current references for pain or "inflammation". Honey & cinnamon are recommended as an option for arthritis pain. In this case, the record does not document conditions requiring this medical food nor is there conclusive evidence for the value of all the combined ingredients. Therefore, there is no medical necessity for Theramine. The request is not medically necessary.

Sentra AM #60:

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC) Pain Procedure Summary, updated 05/15/2014

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 Foods

Decision rationale: Sentra AM is a nutritional supplement containing the active ingredients: choline bitartate; glutamic acid; acetyl L-carnitine; and ginkgo biloba as well as a variety of herbals. It is advertised as a medical food for generalized fatigue, fibromyalgia, and cognitive impairment. The Medical treatment Utilization Schedule (MTUS) does not address Sentra AM. The Official Disability Guidelines (ODG) state that medical foods are recommended for specific dietary management of a disease for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Specifically, choline is only recommended for replacement. There is inconclusive evidence that the product is indicated for memory, seizures, or transient ischemic attacks. Glutamate is used for hypochlorhydria and achlorhydria. In this case, the record does not document conditions requiring this medical food nor is there conclusive evidence for the value of the combined ingredients. Therefore, there is no medical necessity for Sentra AM. The request is not medically necessary.

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) Treatment in Workers Compensation (TWC) Pain Procedure Summary, updated 05/15/2014

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 Foods

Decision rationale: Gabadone is a nutritional supplement containing the active ingredients: choline bitartate; glutamic acid; 5-hydroxytryptophan; GABA; and ginkgo biloba as well as a variety of herbals (grape seed extract and cocoa powder). It is advertised as a medical food for sleep disorders associated with depression. The Medical treatment Utilization Schedule (MTUS) does not address Gabadone. The Official Disability Guidelines (ODG) state that medical foods are recommended for specific dietary management of a disease for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. They specifically state that Gabadone is not recommended. Choline is only recommended for replacement. There is inconclusive evidence that the product is indicated for memory, seizures, or transient ischemic attacks. Glutamate is used for hypochlorhydria and achlorhydria. 5-hydroxytryptophan is possibly effective for anxiety disorders, depression, and fibromyalgia. It has been linked to a contaminant that causes eosinophilia-myalgia syndrome. In this case, the record does not document conditions requiring this medical food nor is there conclusive evidence for the value of all the combined ingredients. Therefore, there is no medical necessity for Gabadone. The request is not medically necessary.

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 (ODG) Treatment in Workers Compensation (TWC) Pain Procedure Summary, updated 05/15/2014

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 Foods

Decision rationale: Sentra PM is a nutritional supplement containing the active ingredients: choline bitartate; glutamic acid; acetyl L-carnitine; 5-hydroxytryptophan; and ginkgo biloba as well as a variety of herbals. It is advertised as a medical food for sleep disorders associated with depression. The Medical treatment Utilization Schedule (MTUS) does not address Sentra PM. The Official Disability Guidelines (ODG) state that medical foods are recommended for specific dietary management of a disease for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Specifically, choline is only recommended for replacement. There is inconclusive evidence that the product is indicated for memory, seizures, or transient ischemic attacks. Glutamate is used for hypochlorhydria and achlorhydria. 5-hydroxytryptophan is possibly effective for anxiety disorders, depression, and fibromyalgia. It has been linked to a contaminant that causes eosinophilia-myalgia syndrome. In this case, the record does not document conditions requiring this medical food nor is there conclusive evidence for the value of all the combined ingredients. Therefore, there is no medical necessity for Sentra PM. The request is not medically necessary.