

Case Number:	CM14-0069400		
Date Assigned:	08/06/2014	Date of Injury:	09/24/2009
Decision Date:	10/06/2014	UR Denial Date:	04/24/2014
Priority:	Standard	Application Received:	05/14/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Management 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 is a patient with a date of injury of 9/24/09. A utilization review determination dated 4/24/14 recommends non-certification of Theramine, Sentra AM, Sentra PM, Gabadone, Terocin, Genicin, Somnicin, and topical creams. 3/10/14 medical report identifies right shoulder pain 7-8/10 and left knee pain 5-8/10. These are then reported as 8-9/10 without medication and 4/10 with medication. Topical medications "increase sleep, decrease pain, walk longer, decrease oral medications." No side effects are noted. On exam, there is limited ROM of the right shoulder and left knee. The knee also demonstrates crepitus and a tender medial joint line. Multiple medications were recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

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 (ODG), Treatment Index, 18th Edition (web), 2013, Treatment in Workers Compensation. Pain - Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter, Medical food and Theramine

Decision rationale: Regarding the request for Theramine, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid...is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine." Furthermore, "Gamma-aminobutyric acid (GABA)...is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia." Also, regarding "L-Serine: There is no indication in Micromedex, Clinical Phamacology, or AltMedDex for the use of this product." Lastly, ODG notes that L-Arginine...is not indicated in current references for pain or "inflammation." It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome. Within the documentation available for review, there is no documentation of a condition for which the components of Theramine would be supported. In the absence of such documentation, the currently requested Theramine is not medically necessary.

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 (ODG), Treatment Index, 18th Edition (web), 2013, Treatment in Workers Compensation. Pain - Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter, Medical food

Decision rationale: Regarding the request for Sentra AM, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid...is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine." Within the documentation available for review, there is no documentation of a condition for which the components of Sentra AM would be supported. In the absence of such documentation, the currently requested Sentra AM 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 Index, 18th Edition (web), 2013, Treatment in Workers Compensation. Pain - Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter, Medical food and Sentra PM

Decision rationale: Regarding the request for Sentra PM, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid...is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine." Within the documentation available for review, there is no documentation of a condition for which the components of Sentra PM would be supported. In the absence of such documentation, the currently requested Sentra PM 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 Index, 18th Edition (web), 2013, Treatment in Workers Compensation. Pain - Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter, Medical food and GABAdone

Decision rationale: Regarding the request for GABAdone, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid...is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine." Furthermore, "Gamma-aminobutyric acid (GABA)...is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia." Within the documentation available for review, there is no documentation of a condition for which the components of GABAdone would be supported. In the absence of such documentation, the currently requested GABAdone is not medically necessary.

Terocin 240ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 Page(s): 111-113 OF 127.

Decision rationale: Regarding the request for Terocin 240 ML, California MTUS cites that topical NSAIDs are indicated for "Osteoarthritis and tendinitis, in particular, that of the knee and

elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." Topical lidocaine is "Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica)." Additionally, it is supported only as a dermal patch. Capsaicin is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." Within the documentation available for review, none of the abovementioned criteria have been documented. Furthermore, there is no clear rationale for the use of topical medications rather than the FDA-approved oral forms for this patient. In light of the above issues, the currently requested Terocin 240 ML is not medically necessary.

Flurbi (NAP) Cream- LA 180mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 Page(s): 111-113 of 127.

Decision rationale: Regarding the request for Flurbi (NAP) Cream- LA 180mg, California MTUS cites that topical NSAIDs are indicated for "Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." Within the documentation available for review, none of the abovementioned criteria have been documented. Furthermore, there is no clear rationale for the use of topical medications rather than the FDA-approved oral forms for this patient. In light of the above issues, the currently requested Flurbi (NAP) Cream- LA 180mg is not medically necessary.

Gabacyclotram 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 Page(s): 111-113 of 127.

Decision rationale: Regarding the request for Gabacyclotram 180gm, California MTUS cites that muscle relaxants and antiepilepsy drugs are not supported by the CA MTUS for topical use. Furthermore, there is no clear rationale for the use of topical medications rather than the FDA-approved oral forms for this patient. In light of the above issues, the currently requested Gabacyclotram 180gm is not medically necessary.

Genocin #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 (ODG), Treatment Index, 18th Edition (web), 2013, Treatment in Workers Compensation, Pain - Medical Food.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 Page(s): 50 of 127. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Foods

Decision rationale: Regarding the request for Genicin, California MTUS cites that glucosamine and chondroitin are recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no documentation of any significant arthritis pain. In light of the above issues, the currently requested Genicin is not medically necessary..

Somnicin #30: 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 Index, 18th Edition (web), 2013, Treatment in Workers Compensation, Pain - Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter, Insomnia treatment

Decision rationale: Regarding the request for Somnicin, California MTUS and ODG do not support the use of L-tryptophan, pyridoxine, or magnesium in the management of any of the patient's cited conditions. There is limited support for melatonin in the management of insomnia. Within the documentation available for review, there is no clear description of insomnia, failure of non-pharmacological treatment for this condition, and a clear rationale for the use of all of the components of this compound for this patient. In light of the above issues, the currently requested Somnicin is not medically necessary.