

Case Number:	CM14-0093433		
Date Assigned:	08/08/2014	Date of Injury:	10/14/2013
Decision Date:	10/14/2014	UR Denial Date:	06/04/2014
Priority:	Standard	Application Received:	06/19/2014

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, Pulmonary Diseases 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:

The injured worker is a 19-year-old male who reported an injury on 10/14/2013 after hitting his elbow on a metal bar while at work. The injured worker complained of left elbow/forearm pain with numbness and tingling. The injured worker had a diagnosis of left elbow/forearm fracture. The diagnostics included an X-ray and an MRI that revealed lateral epicondylitis. The past treatments included medication, physical therapy, and a TENS unit. The injured worker rated his pain a 5/10 with medication and 8/10 without medication. The medications included topical cream and Tramadol. The objective findings dated 07/09/2014 of the left elbow revealed a flexion of 140 degrees, extension 0 degrees, supination 70 degrees, pronation 70 degrees, and tender to the left epicondyle. The treatment plan included medications. The Request for Authorization dated 08/08/2014 was submitted with documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Orthopedic consult - left elbow: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM, Chapter 7

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Forearm, Wrist, & Hand Office Visits

Decision rationale: The request for orthopedic consult - left elbow is not medically necessary. The California MTUS/ ACOEM did not address The Official Disability Guidelines recommend office visits for proper diagnosis and return to function of an injured worker. The need for a clinical office visit with a healthcare provider is individualized based upon a review of the patient's concerns, signs and symptoms, clinical stability, and reasonable physician judgment. As patients' conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with the eventual patient independence from the healthcare system through self-care as soon as clinically feasible. The clinical notes indicated that the injured worker had lateral epicondylitis which had resolved on its own. The clinical notes did not indicate the need for an orthopedic consult. As such, the request is not medically necessary.

Terocin pain patch 2 boxes: 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 Salicylate , Topical Analgesic, Lidocaine Page(s): 105, 111, 112.

Decision rationale: The request for Terocin pain patch 2 boxes is not medically necessary. The California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The California MTUS guidelines indicate that topical Lidocaine (Lidoderm) may be 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). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The clinical notes were not evident of peripheral pain. The request did not indicate the frequency or dosage. As such, the request is not medically necessary.

Menthoderm Gel 240mg & Xolindo 2% cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Page(s): 111-113.

Decision rationale: The request for Mentoderm Gel 1240mg & Xolindo 2% cream is not medically necessary. CA MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are

primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The request did not address the frequency, dosage or duration. As such, the request is not medically necessary.

Tens unit-30 day trial with supplies: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 116.

Decision rationale: The request for TENS unit 30-day trial with supplies is not medically necessary. The California MTUS guidelines do not recommend a TENS unit as a primary treatment modality. A one-month home based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration. The results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. There is a lack of documentation indicating significant deficits upon physical exam. The efficacy of the injured worker's previous courses of conservative care was not provided. It was unclear if the injured worker underwent an adequate TENS trial. The request is also unclear as to if the injured worker needed to rent or purchase the TENS unit. Therefore, the request is not medically necessary.

Sentra PM, Quantity 60: Upheld

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

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: The request for Sentra PM, Quantity 60 is not medically necessary. The California MTUS/ ACOEM do not address. The Official Disability Guidelines recommend as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as a food which is formulated to be consumed or administered internally 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. The product must be a food for oral or tube

feeding; the documentation was not evident that the injured worker had a condition that requires tube or oral feeding. The request did not address the frequency. As such, the request is not medically necessary.

Gabadone Quantity 60: Upheld

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

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: The request for Gabadone Quantity 60 is not medically necessary. The California MTUS/ ACOEM do not address. The Official Disability Guidelines recommend as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered internally 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. The product must be a food for oral or tube feeding; the documentation was not evident that the injured worker had a condition that requires tube or oral feeding. The request did not address the frequency. As such, the request is not medically necessary.

Trepadone, Quantity 90: Upheld

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

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: The request for Trepadone, Quantity 90 is not medically necessary. The California MTUS/ ACOEM do not address. The Official Disability Guidelines recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered internally 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." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Per the clinical note, the injured worker did not require tube feeding or meet the criteria for a medical disorder, disease, or condition in which there are distinctive

nutritional requirements. The request did not address the frequency. As such, the request is not medically necessary.

Omeprazole 20mg, Quantity 60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines specific drug list & adverse effects Page(s): 70.

Decision rationale: The request for Omeprazole 20mg, Quantity 60 is not medically necessary. The California MTUS recommends proton pump inhibitors for the treatment of dyspepsia secondary to NSAID therapy. There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. The documentation was not evident that the injured worker had a peptic ulcer or gastrointestinal issues. As such, the request is not medically necessary.

Theramine Quantity 90: Upheld

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

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: The request for Theramine Quantity 90 is not medically necessary. The Official Disability Guidelines recommend as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as a food which is formulated to be consumed or administered internally 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. The product must be a food for oral or tube feeding; the documentation was not evident that the injured worker had a condition that requires tube or oral feeding. The request did not address the frequency. As such, the request is not medically necessary.

Sentra AM, Quantity 60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.marvistahealthcenter.com/medicalfoods/SentraAMProductMonograph.pdf>

Decision rationale: The request for Sentra AM, Quantity 60 is not medically necessary. The California MTUS/ ACOEM or The Official Disability Guidelines do not address. Refer to [marvistahealthcenter.com/medical foods/Sentra AM Product Monograph](http://marvistahealthcenter.com/medical-foods/Sentra-AM-Product-Monograph) Sentra AM is a patented blend of neurotransmitters and neurotransmitter precursors (Choline Bitartrate and Glutamate); activators of precursor utilization (Acetyl-L-Carnitine, glutamate, and cocoa powder); polyphenolic antioxidants (grape-seed extract, hawthorn berry, cocoa powder); an amino acid uptake stimulator (Gingko Biloba); an adenosine antagonist (cocoa powder); and an inhibitor of the attenuation of neurotransmitter production associated with precursor administration (grape-seed extract). As such, the request is not medically necessary.