

Case Number:	CM13-0022146		
Date Assigned:	10/11/2013	Date of Injury:	01/28/2004
Decision Date:	02/03/2014	UR Denial Date:	08/18/2013
Priority:	Standard	Application Received:	09/09/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain 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 physician 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 63-year-old male who reported an injury on 1/28/04. The notes indicate that the patient was initially injured as a result of a fall, and is currently diagnosed with complex regional pain syndrome (CRPS) of the right upper extremity, with notes indicating that the patient has undergone two right elbow surgeries. The patient also has diagnoses of chronic pain syndrome and chronic pain related insomnia, as well as myofascial syndrome and neuropathic pain. The patient most recently was evaluated on 8/5/13 with notes indicating that his pain score was 6-7/10. The notes indicate the patient had complaints of pain to the bilateral shoulders, right arm and redness in the right arm. He also described a flare up of CRPS and that since that time the patient has had a red and swollen arm. The notes indicated the patient was experiencing significant gains in physical therapy with four sessions remaining. The patient also indicated experiencing worsening depression since he discontinued seeing a psychologist. The notes indicate that the patient requires ongoing psychological care in addition to antidepressant medication to help him cope with his chronic pain arising out of his industrial injuries.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 Clonidine 0.2mg with one refill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System. Essential hypertension. Ann Arbor (MI): University of Michigan Health System; 2009 Feb 15

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation the Official Disability Guidelines, and the MedlinePlus Drug Information for Clonidine.

Decision rationale: The California MTUS/ACOEM guidelines do not directly address Clonidine. The Official Disability Guidelines indicate its use in intrathecal delivery systems for pain relief; however, there is only small evidence that this medication provides long-term pain relief, and there have been no studies that have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Also, the ODG states its use as a second line anti-hypertensive medication. Clinical literature states its use as a sympatholytic medication used to treat high blood pressure, ADHD, anxiety/panic disorder, and certain pain conditions. It is classified as a centrally acting α_2 adrenergic agonist. An alternative hypothesis that has been proposed is that Clonidine acts centrally as an imidazoline receptor agonist. The documentation submitted for review indicates that the patient is currently clinically assessed with complex regional pain syndrome of the right upper extremity, as well as with a chronic pain and myofascial pain syndrome. The patient also has neuropathic pain and a recommendation was made for a refill of Clonidine 0.2 mg twice a day to treat chronic regional pain syndrome. However, a review of clinical notes submitted for review fails to provide documentation supporting a diagnosis of CRPS. Furthermore, a report dated 5/10/12 recommended the patient to begin a trial of Clonidine fails to provide any significant documentation of symptoms related to CRPS. Furthermore, the clinical notes from 05/10/2012 indicated that the patient was previously diagnosed with reflex sympathetic dystrophy in 2007 by a pain management physician. However, the clinical documentation of 2007 was not presented for review. Given that the patient's current prescription request for Clonidine is predicated on the diagnosis of CRPS type 1 is not substantiated in clinical documentation, the request is not medically necessary and appropriate.

60 5-HTP: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, and the WebMD information for 5-HTP.

Decision rationale: The California MTUS/ACOEM guidelines do not specifically address 5 HTP. The Official Disability Guidelines state that 5-HTP has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. It has been used in alternative medicine for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches, and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. Clinical literature states 5 HTP is also known as Oxitriptan (INN), and is a naturally occurring amino acid and chemical precursor, as well as a metabolic intermediate in the

biosynthesis of the neurotransmitters serotonin and melatonin from tryptophan. 5-HTP is sold over the counter in the United Kingdom, United States and Canada as a dietary supplement for use as an antidepressant, appetite suppressant, and sleep aid. While there is indication that the patient is currently utilizing 5 HTP until Pristiq is approved, there is a lack of documentation submitted for review to support the recommendation that the patient is currently diagnosed with depression, or to indicate that the patient has nutritional deficits requiring the need for 5 HTP. Given the above, the request is not medically necessary and appropriate.

TGHot ointment, 180gms: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Effectiveness of topical administration of opioids in palliative care: a systemic review." B. LeBon, G Zeppetella, IJ Higginson - Journal of pain and symptoms, 2009 - Elsevier

Decision rationale: The California MTUS/ACOEM guidelines do not directly address TGHot ointment. Clinical literature and the clinical nurse case manager notes state that TGHot ointment contains Tramadol 8%, Gabapentin 10%, Menthol and Camphor 2%, and Capsaicin .05%. The MTUS states that topical analgesics are largely experimental in use, with few randomized controlled trials to determine efficacy or safety; also, 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 MTUS states that Gabapentin is not recommended as there is no peer-reviewed literature to support its use. The MTUS also states that Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations of Capsaicin are generally available as a 0.025% formulation and a 0.075% formulation; however, there have been no studies of a 0.0375% formulation of Capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Also, the MTUS does not specifically address opioid analgesics in topical formulations. However, peer reviewed literature states that there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. While the documentation submitted for review indicates that the patient is currently prescribed TGHot ointment for topical administration related to pain complaints, the current request for the medication is not supported as guidelines do not recommend the use of capsaicin if formulation is greater than 0.075%, nor do the guidelines recommend the use of Gabapentin in a topical formulation due to a lack of peer reviewed literature and recent peer reviewed literature does not support the recommendation for

the use of topical opioids due to the deficiency of higher quality evidence in the role of topical opioids. Given the above, the request is not medically necessary and appropriate.