

Case Number:	CM14-0094929		
Date Assigned:	07/25/2014	Date of Injury:	12/31/1996
Decision Date:	09/30/2014	UR Denial Date:	06/10/2014
Priority:	Standard	Application Received:	06/23/2014

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 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 44 year old female who sustained an injury on 12/31/96 due to unknown mechanism of injury resulting in complaints of chronic neck and left shoulder pain. Prior treatment has included injections for the left shoulder and multiple medications to include Butrans patches, Norco, and Tramadol for pain control. The injured worker was also utilizing medical foods for anxiety and insomnia as well as for neuropathic pain. The injured worker was also being provided a topical compounded medication for neuropathic symptoms. As of 02/20/14, the injured worker reported pain being controlled with medications at 6/10 in intensity. Without medications, the injured worker's pain was as high as 8/10. Physical examination was limited with no specific findings noted. The injured worker described shooting pain in the left upper extremity. Theramine was prescribed at this evaluation for neuropathic pain and Gabadone was continued for anxiety. Follow up on 03/13/14 noted continuing pain control with the currently prescribed medications. No specific physical examination findings were noted other than a positive EAST test for right hand numbness. Medications were continued at this evaluation. Follow up on 04/15/14 noted no change in the injured worker's complaints with continuing radiating pain to the upper extremities. The injured worker was still obtaining good pain relief with medications. No specific findings on physical examination were noted. Tramadol was discontinued at this evaluation and Norco was decreased to 10/325mg twice daily. Butrans patches were continued at this evaluation. The injured worker was instructed to utilize Gabadone for insomnia at this evaluation to determine if this would help her sleep. The initial request for Percura #120, Sentra AM #60, and Fluororflex Ointment 240gm was initial non-certified on 06/09/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Percura #120 (No Other Information Provided): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Percura - Medical Food, Official Disability Guidelines (ODG) Pain (Chronic).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Herbal and other preparations. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence.

Decision rationale: As noted in ACOEM guidelines, there are many treatments that have been attempted to treat chronic pain conditions, including some interventions that might be classified as complementary or alternative methods or dietary supplements, etc. (Sherman 05; Wolsko 03) A few of these interventions include homeopathic, herbal, and naturopathic treatments. In addition, the complementary and alternative methods, vitamins or dietary supplements have also been attempted as treatments for chronic pain conditions. Most of these interventions do not have any quality evidence of efficacy (Gagnier 07; Young 06) and there is some controversy surrounding the issue of the value of placebo effects on healing. (Kaptchuk 02) As there are many interventions shown to be efficacious for the treatment of acute and/or chronic pain, it is strongly recommended that patients be treated with therapies proven to be efficacious, whether the intervention is or is not considered complementary. Percura is a medical food consisting of a proprietary blend of amino acids in specific proportions, for the dietary management of the altered metabolic processes associated with pain, inflammation and loss of sensation due to peripheral neuropathy. Medical foods are not recommended for use. There is no indication the injured patient has failed other forms of medication management requiring the use of medical foods. The dose, frequency, and number of refills were not provided. As such, the request for Percura #120 (No Other Information Provided) cannot be recommended as 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): Sentra, Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Sentra PM&ç.

Decision rationale: As noted in ACOEM guidelines, there are many treatments that have been attempted to treat chronic pain conditions, including some interventions that might be classified as complementary or alternative methods or dietary supplements, etc. (Sherman 05; Wolsko 03) A few of these interventions include homeopathic, herbal, and naturopathic treatments. In addition, the complementary and alternative methods, vitamins or dietary supplements have also been attempted as treatments for chronic pain conditions. Most of these interventions do not have

any quality evidence of efficacy (Gagnier 07; Young 06) and there is some controversy surrounding the issue of the value of placebo effects on healing. (Kaptchuk 02) As there are many interventions shown to be efficacious for the treatment of acute and/or chronic pain, it is strongly recommended that patients be treated with therapies proven to be efficacious, whether the intervention is or is not considered complementary. Sentra is intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. Medical foods are not recommended for use. There is no indication the injured patient has failed other forms of medication management requiring the use of medical foods. The dose, frequency, and number of refills were not provided. As such, the request Sentra AM #60 cannot be recommended as medically necessary.

Fluororflex Ointment 240gm: 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) Pain (Chronic).

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

Decision rationale: As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. This compound contains flurbiprofen and cyclobenzaprine which have not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore Fluororflex Ointment 240gm cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.