MAXIMUS Federal Services

Case Number:	CM14-0051356		
Date Assigned:	08/06/2014	Date of Injury:	02/14/2004
Decision Date:	10/14/2014	UR Denial Date:	02/21/2014
Priority:	Standard	Application Received:	03/21/2014

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 Family 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 36 year old female injured on 02/14/04 due to an undisclosed mechanism of injury. Neither the specific injuries sustained nor the initial treatments rendered were discussed in the documentation provided. Diagnoses include thoracic sprain, lumbar spine sprain, headache, disorders of bursa, tendons, and left shoulder region, sprain of unspecified site of left shoulder and upper arm, myalgia, and myositis unspecified, anxiety, sleep disturbance and displacement of lumbar intervertebral disc without myelopathy. Clinical note dated 01/16/14 indicated the injured worker presented complaining of intermittent pain in the head rated at 3/10 and the injured worker feeling tired. The injured worker also complained of upper and low back pain rated at 8/10 with associated stiffness and muscle spasm. The injured worker reported due to sleep difficulty the injured worker has had psychological/emotional reaction to include frustration, depression, anger, and high anxiety. Physical examination of the left shoulder revealed nonspecific tenderness and supraspinatus resistance test, Speed's bicipital tendonitis, and impingement maneuver revealed pain to the left shoulder. Lumbar spine examination revealed normal deep tendon reflexes bilaterally, no loss of sensation, paraspinal tenderness bilaterally, and pain with range of motion. The injured worker reported increased numbness of the legs; however, no abnormalities were noted on physical examination. Clinical note dated 01/17/14 indicated the injured worker presented complaining of burning, radicular low back pain and muscle spasm rated at 7-10/10. The injured worker reported symptoms persist; however, medications offer temporarily relief of pain and improve ability to have restful sleep. Lumbar spine exam revealed ability to heel toe walk, tenderness to palpation of the lumbar paraspinal muscles and over the lumbosacral junction, decreased range of motion, straight leg raise positive bilaterally, sensation to pinprick and light touch slightly diminished, motor strength of the bilateral lower extremities slightly decreased secondary to pain. Treatment plan included

acupuncture and prescription medications to include compounded Ketoprofen, compounded Cyclophene, Dicopanol, Deprizane, Fanatrex, Tabradol, and Synapryn. The initial request was non-certified on 02/21/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Ketoprofen 20% in PLO Gel, 120 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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. Ketoprofen has 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. As it does not meet established and accepted medical guidelines, the Compounded Ketoprofen 20% in PLO Gel, 120 grams cannot be recommended as medically necessary.

Coumpounded Cyclophene 5% in PLO Gel, 120 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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. Cyclobenzaprine has 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 Compounded Coumpounded Cyclophene 5% in PLO Gel, 120 grams cannot be recommended as medically necessary.

Synapryn 10mg/ml oral suspension, 500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 93-94, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

Decision rationale: Synapryn contains tramadol and glucosamine. There is no indication in the documentation the injured worker has been diagnosed with osteoarthritis requiring the use of glucosamine. Moreover, there is no evidence in the documentation the injured worker is unable to swallow and requires the suspension form of this medication versus of the pill form of this medication. As such, the request for Synapryn 10mg/ml oral suspension, 500ml cannot be recommended as medically necessary.

Trabradol 1mg/ml oral suspension, 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41, 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

Decision rationale: Tabradol contains cyclobenzaprine, methylsulfonylmethane, and other proprietary ingredients. Methylsulfonylmethane is considered a nutritional supplement and is regulated by the United States Federal Drug Administration; it has not been approved for the treatment of osteoarthritis. Cyclobenzaprine is recommended as a second-line option for short-term (less than two weeks) treatment of acute low back pain and for short-term treatment of acute exacerbations in patients with chronic low back pain. Moreover, there is no evidence in the documentation the injured worker is unable to swallow and requires the suspension form of this medication versus of the pill form of this medication. As such, the request for Trabradol 1mg/ml oral suspension, 250ml cannot be recommended as medically necessary.

Deprizine 15mg/ml oral suspension, 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): (electronically cited).

Decision rationale: Deprizine contains ranitidine is an H2RA which is utilized in the prophylactic treatment of gastritis associated with non-steroidal anti-inflammatory drug use. There is no indication that the injured worker cannot benefit from over-the-counter proton pump inhibitors if required. Moreover, there is no evidence in the documentation the injured worker is unable to swallow and requires the suspension form of this medication versus of the pill form of

this medication. As such, the request for Deprizine 15mg/ml oral suspension, 250ml cannot be recommended as medically necessary.

Dicopanol (diphenhydramine) 5mg/ml oral suspension, 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.nlm.nih.gov, diphenhydramine

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), Insomnia treatment

Decision rationale: Dicopanol contains diphenhydramine and other proprietary ingredients and is used for the treatment of insomnia. Additionally, the injured worker has no documented diagnosis of insomnia that has failed attempts at previous prescription medications or behavior modification. Moreover, there is no evidence in the documentation the injured worker is unable to swallow and requires the suspension form of this medication versus of the pill form of this medication. As such, the request for Dicopanol (diphenhydramine) 5mg/ml oral suspension, 150ml cannot be recommended as medically necessary.

Fanatrex (Gabapentin) 25mg/ml oral suspension, 420mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs Page(s): 16-22.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 49.

Decision rationale: Fanatrex contains gabapentin which is an option for neuropathic pain. Objective findings fail to establish the presence of neuropathy. Moreover, there is no evidence in the documentation the injured worker is unable to swallow and requires the suspension form of this medication versus of the pill form of this medication. As such, the request for Fanatrex (Gabapentin) 25mg/ml oral suspension, 420mg cannot be recommended as medically necessary.