MAXIMUS Federal Services

Case Number:	CM14-0046691		
Date Assigned:	07/02/2014	Date of Injury:	06/20/2013
Decision Date:	08/21/2014	UR Denial Date:	04/04/2014
Priority:	Standard	Application Received:	04/14/2014

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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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:

Patient is a 49-year-old male who has submitted a claim for post-traumatic osteoarthritis of the right hip, bilateral inguinal hernia, chondromalacia patella of the left knee, partial tear of calcaneofibular ligament and ATFL of the left ankle, Achilles tendinitis, peroneal tendinitis, post-traumatic osteoarthritis of the left ankle, and sleep disorder associated with an industrial injury date of 06/20/2013. Medical records from 2013 to 2014 were reviewed. Patient complained of pain at the right hip, left knee, left ankle, and right foot, graded 5 to 7/10 in severity. Intake of medications provided temporary relief of symptoms and improvement in sleep quality. Physical examination of the right hip showed tenderness at the greater trochanter and restricted motion. Examination of the left knee and ankle showed limited range of motion and tenderness, without deformity or instability. Sensation was diminished at the right foot, with noted weakness. Treatment to date has included physical therapy, acupuncture, shockwave, and medications such as ketoprofen gel, Synapryn, Tabradol, Deprizine, compound cyclophene, Dicopanol, and Fanatrex oral suspension. Utilization review from 04/08/2014 denied the requests for compound medication-Ketoprofen 20% in PLO gel 120 gms. prescribed on 2.24.14 and Cyclophene 5% in PLO gel 120 GMS, prescribed on 2.24.14 because there was no documentation that patient had failed a trial of oral antiepileptic or antidepressant medications; denied Synapryn 10 mg/1ml oral suspension 500 ml prescribed on 2.24.14 and Tabradol 1mg/ml oral suspension 250 ml, prescribed on 2.24.14 because there was no evidence that the patient could not tolerate tablet formulation; denied Deprizine 15mg/ml oral suspension prescribed on 2.24.14 because there was no documentation that patient had gastrointestinal upset; denied Dicopanol diphenhydramine 5mg/ml oral suspension 150 ml, prescribed on 2.24.14 because there was no evidence of sleep disorders or insomnia; and denied Fanatrex (Gabapentin)

25mg/ml oral suspension 420ml, prescribed on 2.24.14 because neuropathic pain was not evident.

IMR ISSUES, DECISIONS AND RATIONALES

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

compound medication-Ketoprofen 20% in PLO gel 120 gms. prescribed on 2.24.14: Upheld

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

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

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, ketoprofen is not recommended for topical use, as there is a high incidence of photo contact dermatitis. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. In this case, ketoprofen gel was prescribed for inflammation. However, it is unclear if patient had intolerance to oral medications that may necessitate topically formulated drugs. Moreover, Ketoprofen is not recommended for topical use as stated above. There is no discussion concerning need for variance from the guidelines. Therefore, the request for compound medication-Ketoprofen 20% in PLO gel 120 gms. prescribed on 2.24.14 was not medically necessary.

Synapryn 10 mg/1ml oral suspension 500 ml prescribed on 2.24.14: 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: Synapryn http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=20039.

Decision rationale: The California MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. A search of online resources revealed that Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. Additionally, this drug has not been found by FDA to be safe and effective, and is not approved by the FDA. In this case, Synapryn was prescribed due to unresponsiveness to first-line medications. However, medical records submitted and reviewed failed to provide data concerning the drug that the patient had tried and failed. The medical necessity cannot be established due to insufficient information. Moreover, the requested drug is generally not recommended as stated above. Therefore, the request for Synapryn 10 mg/1ml oral suspension 500 ml prescribed on 2.24.14 was not medically necessary.

Tabradol 1mg/ml oral suspension 250 ml, prescribed on 2.24.14: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Tabradol http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434.

Decision rationale: Tabradol is cyclobenzaprine hydrochloride with MSM in oral suspension. The California MTUS Chronic Pain Medical Treatment Guidelines state that cyclobenzaprine is a skeletal muscle relaxant and a CNS depressant that is recommended as a short-course therapy. The effect is greatest in the first 4 days of treatment. In this case, there is no documentation regarding intolerance to cyclobenzaprine in tablet form. In addition, Methylsulfonylmethane (MSM) is not FDA approved. There is no discussion concerning the need for variance from the guidelines. Moreover, muscle spasm was not evident in the progress reports submitted. Therefore, the request for Tabradol 1mg/ml oral suspension 250 ml, prescribed on 2.24.14 was not medically necessary.

Deprizine 15mg/ml oral suspension prescribed on 2.24.14: 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: Depirizine http://www.drugs.com/pro/deprizine.html.

Decision rationale: The California MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. According to FDA, Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. In this case, Deprizine was prescribed as prophylactic treatment for gastric ulcers. However, patient had no subjective complaints or objective findings pertaining to the gastrointestinal system that may warrant prescription of such. Moreover, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Deprizine 15mg/ml oral suspension prescribed on 2.24.14 was not medically necessary.

Compound Cyclophene 5% in PLO gel 120 gms., prescribed on 2.24.14: Upheld

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

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

Decision rationale: Cyclophene contains cyclobenzaprine hydrochloride and other proprietary ingredients. As noted on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and Gabapentin and other antiepilepsy drugs are not recommended for topical applications. In this case, patient was prescribed cyclophene as treatment for muscle spasms. However, progress reports submitted failed to provide evidence of such. Moreover, there is no documentation regarding intolerance to or failure of first-line pain medications that may warrant a topically formulated drug. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for Cyclophene 5% in PLO gel 120 GMS, prescribed on 2.24.14 was not medically necessary.

Dicopanol diphenhydramine 5mg/ml oral suspension 150 ml, prescribed on 2.24.14: 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: Dicopanol http://www.drugs.com/cdi/diphenhydramine.html.

Decision rationale: The California MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Dicopanol is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. In this case, patient was prescribed Dicopanol for insomnia. Although this patient reports issues with sleep, there is no rationale provided for the medical necessity of an oral suspension. Moreover, there was no discussion concerning sleep hygiene and if non-pharmacologic management had been attempted first. Therefore, the request for Dicopanol diphenhydramine 5mg/ml oral suspension 150 ml, prescribed on 2.24.14 was not medically necessary.

Fanatrex (gabapentin) 25mg/ml oral suspension 420ml, prescribed on 2.24.14: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-18.

Decision rationale: The California MTUS Chronic Pain Medical Treatment Guidelines state that Fanatrex is gabapentin with other proprietary ingredients in oral suspension. Gabapentin is used to treat diabetic painful neuropathy and postherpetic neuralgia. In this case, patient was prescribed Fanatrex for chronic neuropathic pain. However, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml, prescribed on 2.24.14 was not medically necessary.