

Case Number:	CM14-0089404		
Date Assigned:	07/23/2014	Date of Injury:	11/10/2009
Decision Date:	09/22/2014	UR Denial Date:	05/28/2014
Priority:	Standard	Application Received:	06/13/2014

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 Physical Medicine & Rehabilitation, and is licensed to practice in Illinois. 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 61-year-old male who reported injury after he fell 11/10/2009. The clinical note dated 03/29/2014 indicated diagnoses of cervical spine pain, cervical spine radiculopathy, cervical disc displacement, bilateral shoulder internal derangement, labral tear of the right shoulder, low back pain, radiculopathy of the lumbar region, lumbar disc displacement, anxiety disorder, and sleep disorder. The injured worker reported burning, radicular neck pain and muscle spasms that were constant and moderate to severe, rated 5/10 to 6/10. The injured worker reported burning to the bilateral shoulder, pain greater on the left, rated 5/10 to 6/10 that was constant and moderate to severe. The injured worker reported burning, radicular low back pain and muscle spasms, described as constant and moderate to severe, rated 5/10 to 6/10. The injured worker reported difficulty sleeping, feeling anxious, and problems with intimacy. The injured worker reported the medications offered him temporary relief of pain and improved his ability to have restful sleep. The injured worker denied any problems with medications and reported the pain was also alleviated by activity restrictions. On physical examination of the cervical spine, there was tenderness over the cervical paraspinal muscles suboccipital regions, scalene, rhomboids, and trapezius muscles with decreased range of motion. The examination of the bilateral shoulder revealed decreased range of motion, Neer's impingement sign, Kennedy Hawkins, and drop arm bilaterally. The injured worker had diminished sensation in both upper extremities with decreased motor strength. The examination of the lumbar spine revealed tenderness over the lumbar paraspinal muscles with trigger points and over the paraspinal process at L4-S1 with trigger points at the L4-5. There was tenderness over the paraspinal with decreased range of motion. A positive straight leg raise at 40 degrees bilaterally. The injured worker had a positive flip test and Kemp test bilaterally with slight decreased sensation in both lower extremities. The injured worker's motor strength was decreased in both lower extremities.

The injured worker's treatment plan included a referral for orthopedic surgery and a follow-up appointment in 4 weeks. The injured worker's prior treatments included medication management. The injured worker's medication regimen was not provided for review. The provider submitted a request for compounded ketoprofen, compounded Cyclophene, and compounded Synapryn. A Request for Authorization was not submitted for review to include the date the treatment was requested.

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, QTY: 120 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain, Compounded Drugs.

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

Decision rationale: The request for Ketoprofen 20% in PLO Gel, QTY: 120 gm is not medically necessary. The California MTUS guidelines indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. It is not indicated if the injured worker had tried and failed antidepressants and anticonvulsants. In addition, ketoprofen is not currently FDA approved for topical application. Per the guidelines, any compounded product that contains at least 1 drug or drug class that is not recommended, is not recommended. Moreover, it was not indicated whether the injured worker had been utilizing this medication, and if so, for how long. Additionally, there is lack of documentation of efficacy and functional improvement with the use of this medication. Furthermore, the request does not indicate a frequency for this medication. Therefore, the request for Compounded Ketoprofen 20% in PLO Gel, 120 grams is not medically necessary.

Compounded Cyclophene 5% in PLO Gel, QTY: 120 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain, Compounded Drugs.

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

Decision rationale: The request for Compounded Cyclophene 5% in PLO Gel, QTY: 120 gm is not medically necessary. The California MTUS guidelines indicate that topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and 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. It was not indicated if the injured worker had tried and failed antidepressants and anticonvulsants. In addition, the guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant as there is there no evidence for use of any other muscle relaxant as a topical products. Per the guidelines, any compounded product that contains at least 1 or drug class that is not recommended, is not recommended. In addition, the request did not indicate a frequency for this medication. Moreover, the provider did not indicate a rationale for the request. Additionally, it was not indicated if this was a trial use or if this injured worker had been utilizing this medication. If so, there is a lack of documentation of efficacy and functional improvement with the use of this medication. Therefore, the request for Compounded Cyclophene 5% in PLO Gel, 120 grams is not medically necessary.

Compounded Synapryn (Tramadol) 10mg/1ml, 500ml/Tabradol (Cyclobenzaprine) 1mg/ml, 250 ml/ Deprizine (Ranitidine) 15 mg/ml, 250 ml/Dicopanol (Diphenhydramine) 5mg/ml, 150 ml/Fanatrex (Gabapentin) 25 mg/ml, 420ml: 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, Compounded Drugs.

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

Decision rationale: The request for Compounded Synapryn (Tramadol) 10mg/1ml, 500ml/Tabradol (Cyclobenzaprine) 1mg/ml, 250 ml/ Deprizine (Ranitidine) 15 mg/ml, 250 ml/Dicopanol (Diphenhydramine) 5mg/ml, 150 ml/Fanatrex (Gabapentin) 25 mg/ml, 420ml is not medically necessary. The California MTUS guidelines indicate that topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and 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. It was not indicated if the injured worker had tried and failed antidepressants and anticonvulsants. In addition, a thorough search of FDA.gov did not indicate there was a formulation of topical Tramadol that had been FDA approved. Additionally, the guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant as there is there no evidence for use of any other muscle relaxant as a topical products. Moreover, gabapentin is not recommended. There is no peer review literature to support its use. Per the guidelines, any compounded product that contains at least 1 drug or drug class that is not recommended, is not recommended. Furthermore, the request did not indicate a frequency. Additionally, it was not indicated the injured worker had been utilizing this medication, and if so, there is a lack of documentation of efficacy and functional improvement with the use of this medication. Therefore, the request for Compounded Synapryn (Tramadol) 10mg/1ml, 500ml/Tabradol (Cyclobenzaprine) 1mg/ml, 250 ml/ Deprizine (Ranitidine) 15 mg/ml, 250 ml/Dicopanol (Diphenhydramine) 5mg/ml, 150 ml/Fanatrex (Gabapentin) 25 mg/ml, 420ml is not medically necessary.