MAXIMUS Federal Services

Case Number:	CM13-0030788		
Date Assigned:	11/27/2013	Date of Injury:	03/31/2013
Decision Date:	11/26/2014	UR Denial Date:	09/10/2013
Priority:	Standard	Application Received:	10/01/2013

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 and Rehabilitation, 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 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:

This is a 39-year-old male who sustained a remote industrial injury on 03/31/13 diagnosed with left shoulder pain rule out internal derangement; status post left wrist closed fracture with residual pain, and sleep disorder. The mechanism of injury occurred when the patient flipped a four wheeler vehicle and landed on his shoulder, fracturing one or two bones in the wrist. The request for compounded Ketoprofen 20% in PLO gel, 120gms was non-certified at utilization review due to the lack of support of the use of this medication by guidelines and the lack of evidence that the patient has failed first-line oral medications, while the request for compounded Cyclophene 5% in PLO gel, 120gms was also non-certified at utilization review due to this medication containing cyclobenzaprine which is not indicated for topical use per guidelines. The requests for Synapryn 10mg/1ml 500ml; 5ml three times daily and Tabradol 1mg/mg 250ml; 5ml 2-3 times daily were non-certified at utilization review due to the lack of documentation that the patient has failed first line medications, the ingredients these medications contain, and the lack of rationale explaining why these medications would be indicated as necessary. Similarly, the requests for Deprizine 15mg/ml 250ml; 10ml once daily, Dicopanol 5mg/ml 150ml; 1ml at bedtime, and Fanatrex 25mg/ml 420ml; 5ml three times a day were non-certified at utilization review due to the lack of documentation of diagnoses related to gastrointestinal issues, insomnia, and neuropathic pain to indicate the use of these medications. The requests for physical therapy and chiropractic care were also non-certified at utilization review due to the lack of documentation of the number of previous sessions of each of these treatments, the lack of physical exam findings, and the lack of specifying whether the patient obtained any functional improvement with prior treatments. Lastly, the request for periodic urinalysis toxicology evaluation was non-certified at utilization review due to the lack of evidence that the patient is at high risk of medication abuse and the previous compounds containing tramadol and

cyclobenzaprine were also non-certified. The most recent progress note provided is 08/19/14. The patient complains primarily of left shoulder pain that radiates down the arm to the fingers associated with muscle spasms and rated as a 6/10. The patient also complains of residual pain and muscle spasms in the left wrist rated as a 6/10, weakness, numbness, tingling and pain radiating to the hands and fingers, and difficulty sleeping. Physical exam findings reveal tenderness to palpation at the AC joint and deltoid muscle of the left shoulder, palpable periscapular tenderness on the left, restricted range of motion of the left shoulder, tenderness at the carpal tunnel and first dorsal extensor muscle compartment of the left wrist, decreased range of motion of the left wrist, diminished sensation over the C5, C6, C7, C8 and T1 dermatomes, and decreased muscle strength of a 4/5 in the muscle groups of the left upper extremity. Current medications include: Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Capsaicin, Flurbiprofen, Menthol, Cyclobenzaprine, and Gabapentin. It is noted that the patient's medications offer temporary relief of pain and improve the ability to have restful sleep. The treating physician is requesting medication refills and 18 sessions of physical therapy and chiropractic treatment. Provided documents include previous progress reports, requests for authorization, letters of medical necessity, a sleep profile study report, a cardio-respiratory diagnostic testing reporting, a sudomotor function assessment diagnostic report, previous utilization reviews, an ARCON computerized strength test, and an agreed medical evaluation. The patient's previous treatments include chiropractic, physical therapy, acupuncture, and medications. Diagnostic studies provided include an EMG/NCV of the bilateral upper extremities, performed on 04/02/14. The findings of this study reveal prolonged sensorimotor latencies of the bilateral median and right ulnar nerves.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% In Plo Gel, 120gms: Upheld

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

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

Decision rationale: According to MTUS Chronic Pain Medical Treatment Guidelines on topical analgesics, non-steroidal anti-inflammatory drugs (NSAIDs) are indicated for "Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." In the current clinical setting, there is no documentation of a diagnosis of osteoarthritis or tendinitis for this patient. Further, the treating provider does not provide a rationale as to why the patient requires topical NSAIDs versus traditional oral agents. Lastly, guidelines highlight that Ketoprofen is currently not approved by the FDA for topical application. For these reasons, the request for Ketoprofen 20% in PLO gel, 120gms is not medically necessary.

Compound Cyclophene 5% In Plo Gel, 120gms: Upheld

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

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

Decision rationale: The California MTUS Chronic Pain Medical Treatment Guidelines state, "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 is not recommended." In this case, the ingredient of Cyclobenzaprine is not supported by guidelines. As there is no evidence to support the topical application of muscle relaxants such as Cyclobenzaprine as efficacious, medical necessity is not supported and the request for compound Cyclophene 5% in PLO gel, 120gms is not medically necessary.

Synapryn (10mg/1ml) 500ml Take 5ml Three Times Daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 90-91.

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

Decision rationale: Synapryn contains the ingredients of Tramadol, Glucosamine, and other non-specified proprietary ingredients. According to the Official Disability Guidelines, compound drugs are "not recommended as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in Official Disability Guidelines." In the documents provided, the treating physician does not indicate the failure of first-line FDA approved drugs. Further, provided documentation does not specify why a compounding kit is necessary instead of the standard oral formulation. Thus, medical necessity is not supported and the request for Synapryn 10mg/1ml 500ml; 5ml three times daily is not medically necessary.

Tabradol 1mg/Mg 250ml, Take 5ml 2-3 Times Daily: Upheld

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

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

Decision rationale: Tabradol contains the ingredients of Cyclobenzaprine, Methylsulfonylmethane, and other non-specified proprietary ingredients. According to Official Disability Guidelines, Compound Drugs are "not recommended as a first-line therapy for most

patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in Official Disability Guidelines." In the documents provided, the treating physician does not indicate the failure of first-line FDA approved drugs. Further, provided documentation does not specify why a compounding kit is necessary instead of the standard oral formulation. Thus, medical necessity is not supported and the request for Tabradol 1mg/mg 250ml; 5ml 2-3 times daily is not medically necessary.

Deprizine 15mg/Ml 250ml, Take 10ml Once Daily: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/formucare-ranitidine.html

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

Decision rationale: Deprizine contains the ingredients of Ranitidine and other non-specified proprietary ingredients. According to Official Disability Guidelines, Compound Drugs are "not recommended as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in Official Disability Guidelines." In the documents provided, the treating physician does not indicate the failure of first-line FDA approved drugs, or a diagnosis of gastrointestinal issues for which Ranitidine is prescribed. Further, provided documentation does not specify why a compounding kit is necessary instead of the standard oral formulation. Thus, medical necessity is not supported and the request for Deprizine 15mg/ml 250ml; 10ml once daily is not medically necessary.

Dicopanol 5mg/Ml, Take 1ml At Bedtime: Upheld

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

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

Decision rationale: Dicopanol contains the ingredients of Diphenhydramine and other non-specified proprietary ingredients. According to Official Disability Guidelines, Compound Drugs are "not recommended as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in Official Disability Guidelines." In the documents provided, the treating physician does not indicate the failure of first-line FDA approved drugs. Further, provided documentation does not specify why a compounding kit is necessary instead of the

standard oral formulation. Thus, medical necessity is not supported and the request for Dicopanol 5mg/ml 150ml; 1ml at bedtime is not medically necessary.

Fanatrex 25mg/Ml 420ml, Take 5ml TID: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: Fanatrex contains the ingredients of Gabapentin and other non-specified proprietary ingredients. According to Official Disability Guidelines, Compound Drugs are "not recommended as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in Official Disability Guidelines." In the documents provided, the treating physician does not indicate the failure of first-line FDA approved drugs. Further, provided documentation does not specify why a compounding kit is necessary instead of the standard oral formulation. Thus, medical necessity is not supported and the request for Fanatrex 25mg/ml 420ml; 5ml three times a day is not medically necessary.

Physical Therapy (Unspecified Frequency or Duration): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 98-99.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98-99.

Decision rationale: According to California MTUS Chronic Pain Medical Treatment Guidelines, "Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels." Provided documentation notes that the patient has participated in physical therapy in the past. However, the number of sessions completed and any functional improvement obtained as a result is not delineated. Further, the treating physician does not document limitations that would necessitate more physical therapy sessions over the patient continuing therapy in a safe home exercise program. Lastly, the frequency/duration of the treatment and the body part intended for treatment is not specified in the request. For these reasons, medical necessity is not supported and the request for Physical Therapy is not medically necessary.

Chiropractic Therapy (Unspecified Frequency or Duration): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Guidelines Page(s): 98-99.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58-60.

Decision rationale: The California MTUS Chronic Pain Medical Treatment Guidelines recommend a maximum duration of 8 weeks of chiropractic sessions with the option of more sessions with evidence of objective functional benefit. In this case, provided documentation highlights the patient has undergone chiropractic treatment in the past but the duration of treatment and any obtained functional improvement is not provided. Further, the frequency/duration of and the body part intended for treatment is not specified in the request. As such, the medical necessity for the request of Chiropractic Therapy cannot be supported. Therefore, this request is not medically necessary.

Periodic UA Toxicology Evaluation: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, screening of addiction (tests); Opioids, steps to avoid m.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Urine drug testing (UDT)

Decision rationale: The California MTUS Chronic Pain Medical Treatment Guidelines and Official Disability Guidelines support urine drug screening/toxicology testing for patients undergoing chronic opioid therapy or at risk for drug abuse. According to Official Disability Guidelines, "Frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument." Within this risk stratification, a patient is determined to be at low, moderate, or high risk. In this case, the treating physician does not thoroughly explain how the patient is at moderate/high risk for aberrant behavior, which would warrant frequent testing. Further, the patient's requested medications are recommended for non-certification and the treating physician does not specify that the patient is at a high risk for drug abuse, so urine toxicology screening does not appear appropriate without a specific explanation for why testing is necessary. Without this explanation, medical necessity is not supported and therefore the request for Periodic UA Toxicology Evaluation is not medically necessary.