MAXIMUS Federal Services

Case Number:	CM14-0124572		
Date Assigned:	09/25/2014	Date of Injury:	03/01/2014
Decision Date:	12/10/2014	UR Denial Date:	07/28/2014
Priority:	Standard	Application Received:	08/06/2014

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 and Rehabilitation, has a subspecialty in Pain Management 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 40-year-old male who sustained an injury on 3/1/14. As per the report of 8/13/14, he complained of constant mild lower back pain rated at 6/10 and pain in hands, wrists, and elbows. The lumbar spine exam was normal from this visit but the previous objective findings of the lumbar spine suggested that she had tenderness to palpation of the lumbar paravertebral muscles, Kemp's with pain, straight leg rise (SLR) with pain, and decreased and painful range of motion (ROM). Exam of the wrists and hands revealed extension at 60, flexion at 60, ulnar deviation at 30, and radial deviation at 20 bilaterally. Grip strength was 5/5. Elbow exam showed tenderness over lateral epicondyle, positive Cozen's test, resisted wrist extension for lateral epicondylitis; negative for right, positive for left. Magnetic resonance imaging (MRI) of both hands and wrists on 6/9/14 were normal. X-ray of the lumbosacral spine dated 7/15/14 revealed degenerative disk space narrowing at L4-L5 and L5-S1 with mild spurs at L4 and L5 bodies, and degenerative facet narrowing and sclerosis at L5-S1. SI joints were normal. She appears to be using Naproxen and Camphor-Methyl Salicylate-Menthol patch. Previous treatments have included many sessions of chiropractor therapy for lower back and wrists, including paraffin, LINT therapy and shockwave and analgesics. There was no other information regarding the medications that were requested for authorization. Diagnoses include chronic back pain, overuse disorder of soft tissues, left hand, overuse disorder of soft tissues, right hand improved, and bilateral lateral epicondylitis. The request for Ketoprofen 20% cream 165 grams, Cyclobenzaprine 5% cream 100 grams, Synapryn 10 mg/1 ml oral suspension 500 ml, Trabadol 1 mg/ml oral suspension 250 ml, Dicopanol 5 mg/ml oral suspension, Deprizine 15 mg/ml oral suspension 250 ml was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 165grams: Upheld

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

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

Decision rationale: According to the California Medical Treatment Utilization Schedule (MTUS) guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Furthermore, the California MTUS/Official Disability Guidelines (ODG) states that the only non-steroidal anti-inflammatory drugs (NSAID) that is FDA approved for topical application is diclofenac (Voltaren 1% Gel). Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request is not medically necessary per guidelines.

Cyclobenzaprine 5% cream 100grams: Upheld

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

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

Decision rationale: According to the California Medical Treatment Utilization Schedule (MTUS) guidelines, Topical Analgesics are recommended as a treatment option as these agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. According to the California MTUS guidelines, muscle relaxants, such as cyclobenzaprine, are not recommended in topical formulation. As per the guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Consequently, the request is not medically necessary according to the guidelines.

Synapryn 10mg/1ml oral suspension 500ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-94.

Decision rationale: Synapryn contains tramadol hydrochloride and glucosamine as active ingredients, therefore the Tramadol guidelines were used in this conclusion. Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. It is not clear as to why the commercially available Tramadol (Ultram) has not been prescribed, as there is no evidence of dysphagia to justify for liquid form of medications. Also, there is no mention of reason for prescribing glucosamine, which is a controversial supplement in combination with Tramadol. Therefore, the request for Synapryn is not medically necessary.

Trabadol 1mg/ml oral suspension 250ml: Upheld

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

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

Decision rationale: Per Drug.com, Tabradol is Cyclobenzaprine that is used a muscle relaxant and it helps to relieve the pain, stiffness, and discomfort caused by strains, sprains, or injuries to your muscles. Per California MTUS guidelines, Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. In this case, there is little to no evidence of substantial spasm unresponsive to first line therapy. Furthermore, it is unclear as to why this IW is unable to take commercially available pill form of cyclobenzaprine. Also, chronic use of this medication is not recommended. Therefore, the medical necessity of the request is not established per guidelines.

Dicopanol 5mg/ml oral suspension 150ml: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Insomnia Treatment

Decision rationale: California Medical Treatment Utilization Schedule (MTUS) guidelines do not discuss the issue in dispute and hence Official Disability Guidelines (ODG) have been consulted. As per ODG, Dicopanol (diphenhydramine) is sedating antihistamines have been suggested for sleep aids. Further guidelines indicate "Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance". Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. The records provided do

not adequately discuss the patient's insomnia and justification for diphenhydramine use which fits within guidelines. Therefore, the request is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: As per Drugs.com, Deprizine suspension contains Ranitidine, an H2 receptor antagonist. GI prophylaxis can be considered when there is a history of peptic ulcer disease or risk of serious upper GI events (i.e. concurrent use of ASA, corticosteroids or anticoagulants). Records submitted revealed no documentation of subjective or objective GI events or ulcers to warrant the use of this medication. Additionally, it is unclear why the injured worker (IW) is unable to take commercially available pill or capsule orally. Therefore, the request for Deprizine is not medically necessary or appropriate.