

Case Number:	CM14-0019194		
Date Assigned:	04/21/2014	Date of Injury:	09/25/2012
Decision Date:	08/06/2014	UR Denial Date:	02/14/2014
Priority:	Standard	Application Received:	02/14/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Minnesota. 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 59-year-old male who reported injury on 09/25/2012. The mechanism of injury was caused by the injured worker falling off a truck and injuring his low back and right knee. The clinical documentation indicated the injured worker had been utilizing the topical medications as well as oral medications since 05/2013. The documentation of 01/13/2014 revealed the injured worker sustained injury while working as a recycling crewman while serving time in prison. The injured worker complained of pain in the low back radiating to bilateral legs. The diagnoses included lumbar spine HNP, lumbar facet arthropathy, lumbar radiculopathy, left knee medial meniscal tear, osteoarthritis of the left knee, and right knee degenerative joint disease. The treatment plan included Deprizine, Dicopanapol, Fanatrex Synapryn, Tabradol, Flurbiprofen, Capsaicin, Tramadol, Menthol, and an MRI of the lumbar spine and right knee, pain management consultation for epidural steroid injection, chiropractic treatment for the lumbar spine 3 times a week for 6 weeks, an orthopedic surgeon, and shockwave therapy for 6 treatments for the lumbar spine and Terocin patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETRO: DICOPANAPOL 5MG/ML 150; 1/11/14: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Insomnia Treatments, however, do not specifically address Dicopanol Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Dicopanol>.

Decision rationale: Official Disability Guidelines indicates that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, Dicopanol is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. The clinical documentation indicated the injured worker had been utilizing the medication since 05/2013. There was a lack of documentation of objective functional benefit. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request of retro Dicopanol 5 mg/ml 150; 01/11/2014 is not medically necessary and appropriate.

DIPRIZINE 5MG/ML 250ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69.

Decision rationale: The California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine, which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to provide documented rationale for the requested medication. There was a lack of documentation of efficacy for the requested medication. It was indicated the injured worker had been utilizing the medication since 05/2013. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Deprizine 5 mg/ml 250 ml is not medically necessary and appropriate.

FANATREX 25MG/ML 420ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16.

Decision rationale: California MTUS guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is noted to be an oral suspension of Gabapentin and has not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 5 months. There was a lack of documentation of objective functional benefit. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation of an objective decrease in pain. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Fanatrex 25 mg/ml 420 ml is not medically necessary and appropriate.

SYNAPRYN 10MG/1ML 500ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94.

Decision rationale: The California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included tramadol and glucosamine sulfate. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 5 months. There was a lack of documentation of objective functional benefit and an objective decrease in pain. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Synapryn 10 mg/1 ml 500ML is not medically necessary and appropriate.

TABRADOL 1MG/ML 250ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 4, 64.

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

Decision rationale: The California MTUS indicate that Cyclobenzaprine (Flexeril) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of Cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The clinical documentation submitted for review failed to provide the documented efficacy for the requested medication. The clinical documentation indicated the injured worker had been utilizing the medication for greater than 5 months. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Tabradol 1 mg/ml 250 ml is not medically necessary and appropriate.

TEROCIN PATCHES: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical
Salicylate Topical Analgesic, Lidocaine Page(s): 105, 111, 112.

Decision rationale: The California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety 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. The California MTUS guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. MTUS guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. The clinical documentation submitted for review indicated the injured worker had been utilizing topical creams and ointments for greater than 5 months. In this case, there was a lack of documentation of the efficacy for the requested medication. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency, quantity and strength for the Terocin patches. Given the above and the lack of documentation, the request for Terocin patches is not medically necessary and appropriate.

SHOCKWAVE THERAPY TO THE LUMBAR SPINE: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM.

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: Wang, Ching-Jen. "Extracorporeal shockwave therapy in musculoskeletal disorders." *Journal of orthopaedic surgery and research* 7.1 (2012): 1-8.

Decision rationale: Per Wang, Ching-Jen (2012), "The application of extracorporeal shockwave therapy (ESWT) in musculoskeletal disorders has been around for more than a decade and is primarily used in the treatment of sports related over-use tendinopathies such as proximal plantar fasciitis of the heel, lateral epicondylitis of the elbow, calcific or non-calcific tendonitis of the shoulder and patellar tendinopathy etc." The clinical documentation submitted for review failed to provide documentation of a rationale for the use of extracorporeal shockwave therapy for the lumbar spine. The request as submitted failed to indicate the quantity of sessions being requested. Given the above, the request for shockwave therapy to the lumbar spine is not medically necessary and appropriate.