

Case Number:	CM15-0047169		
Date Assigned:	04/14/2015	Date of Injury:	02/13/2013
Decision Date:	05/29/2015	UR Denial Date:	03/04/2015
Priority:	Standard	Application Received:	03/12/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive Medicine

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 57-year-old male, with a reported date of injury of 02/13/2013. The mechanism of injury was a slip on sand and fall. The diagnoses include cervical spine sprain/strain, rule out herniated nucleus pulposus, rule out cervical radiculopathy, left wrist pain, rule out carpal tunnel syndrome, status post bilateral knee surgery with residual pain, and rule out bilateral knee internal derangement. Treatments to date have included physical therapy, injections, acupuncture, oral medications, an x-ray of the left knee, an x-ray of the right knee, an MRI of the right knee, and an MRI of the cervical spine. The medical report dated 01/27/2015 indicates that the injured worker complained of neck pain with numbness and tingling of the bilateral upper extremities, rated 6 out of 10; left wrist pain, rated 5 out of 10; and bilateral knee pain with residual pain and muscle spasms. The left knee pain was rated 8 out of 10 and the right knee pain was rated 5 out of 10. The physical examination showed tenderness to palpation over the bilateral cervical paraspinal muscles, decreased cervical range of motion, tenderness to palpation of the left wrist, decreased left wrist range of motion, tenderness to palpation over the bilateral medial and lateral joint line to the patellofemoral joint, and decreased bilateral knee range of motion. The injured worker had C5-T1 dermatomal sensation that was decreased and 4/5 strength in all muscle groups of the bilateral upper extremities. The treating physician requested Dicopanol, Cyclobenzaprine, Deprizine, Fanatrex, Terocin patches, physical therapy for the left wrist, transcutaneous electrical nerve stimulation (TENS) unit and supplies, hot/cold unit, an MRI of the left wrist, extracorporeal shock wave therapy (EWST) of the cervical spine,

Synapryn, an x-ray of the left wrist, Ketoprofen, Tabradol, acupuncture for the cervical spine and left wrist, an MRI of the cervical spine, and an x-ray of the cervical spine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dicopanol: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. 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) Official Disability Guidelines (ODG), Pain Chapter, Insomnia Treatments and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence:
<http://www.drugs.com/search.php?searchterm=Dicopanol>.

Decision rationale: The Official Disability Guidelines indicate 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 documentation of difficulty sleeping. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency, quantity and strength for Dicopanol. Given the above, the request is not medically necessary.

Cyclobenzaprine (30-day supply): Upheld

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

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

Decision rationale: The California MTUS guidelines 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. The clinical documentation submitted for review failed to provide a rationale for both an oral and topical form of cyclobenzaprine. The request as submitted failed to indicate the frequency, strength and body part to be treated. The physician documentation indicated the request for cyclobenzaprine gel. Given the above and the lack of documentation, the request is not medically necessary.

Deprizine: 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 Page(s): 69. Decision based on Non-MTUS Citation Drug.com Website (www.drugs.com).

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine, which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by 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 indicate the injured worker had dyspepsia secondary to NSAID therapy. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency, quantity and strength for Deprizine. Given the above, the request is not medically necessary.

Fanatrex: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Drug.com Website (www.drugs.com).

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is an oral suspension of Gabapentin that 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 failed to provide documentation of exceptional factors to warrant nonadherence to the FDA guidelines. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency and quantity, as well as strength for the requested medication. Given the above, the request is not medically necessary.

Terocin Patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105, 111, 112. Decision based on Non-MTUS Citation National Library of Medicine's DailyMed Database (dailymed.nlm.nih.gov).

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate 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 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. The guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. The documentation submitted for review failed to provide documentation the injured worker had a trial and failure of antidepressants and anticonvulsants. 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, quantity and strength for the requested Terocin patches. Given the above, the request is not medically necessary.

Physical Therapy (18 sessions for the left wrist): Upheld

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

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

Decision rationale: The California MTUS Guidelines recommend physical medicine treatment for myalgia and myositis for up to 10 visits. The clinical documentation submitted for review indicated the injured worker had previously undergone physical medicine treatment. The quantity of sessions, as well as objective functional benefit that was received was not provided. There was a lack of documentation of remaining objective functional deficits to support the necessity for supervised therapy. Given the above, the request is not medically necessary.

TENS Unit and Supplies: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS unit Page(s): 114-116.

Decision rationale: The California Medical Treatment Utilization Schedule guideline indicate that a one month trial of a TENS unit is recommended if it is used as an adjunct to a program of evidence-based functional restoration for chronic neuropathic pain. Prior to the trial there must

be documentation of at least three months of pain and evidence that other appropriate pain modalities have been tried (including medication) and have failed. The clinical documentation submitted for review failed to provide documentation of a trial and failure of other pain modalities. The request as submitted failed to indicate whether the unit was for rental or purchase. The quantity of supplies was not provided. Given the above, the request is not medically necessary.

Hot/Cold Unit: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Blue Cross/Blue Shield Medical Policy.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 173.

Decision rationale: The ACOEM Guidelines indicate that local applications of cold packs are appropriate during the first few days of an acute complaint, thereafter application of heat packs is appropriate. The clinical documentation submitted for review failed to provide documentation of exceptional factors to support the necessity for the unit. There was a lack of documentation indicating the injured worker could not utilize local applications of hot and cold packs. The request as submitted failed to indicate whether the unit was for rental or purchase. Given the above, the request is not medically necessary.

MRI of the Left Wrist: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Forearm, Wrist, & Hand Chapter.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 268-269.

Decision rationale: The California MTUS Guidelines recommend that for most injured workers presenting with true hand and wrist problems, unless there has been a 4 to 6 week period of conservative care and observation. There was a lack of documentation indicating the injured worker had a failure of conservative care specifically directed at the left wrist. The prior diagnostic studies of the left wrist were not provided. Given the above, the request is not medically necessary.

ESWT of the Cervical Spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation 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 indicate the injured worker had a sports related overuse tendinopathy. There was a lack of documentation of exceptional factors to warrant non-adherence to peer reviewed literature recommendations. The request as submitted failed to indicate the frequency and the quantity of sessions being requested. Given the above, the request is not medically necessary.

Synapryn: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94. Decision based on Non-MTUS Citation Synapryn Online Drug Insert.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic and they 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. 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. As Tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule chronic pain guidelines recommend opiates for chronic pain. 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 clinical documentation submitted for review failed to provide documentation the injured worker had an inability to swallow or tolerate a pill. The documentation indicated the injured worker was being monitored for aberrant drug behavior and side effects. However, there was a lack of documentation of an objective functional improvement and objective decrease in pain. The documentation indicated the injured worker was utilizing tramadol as 1 of the current medications. There was a lack of documentation indicating a necessity for 2 medications with tramadol as an ingredient. The request as submitted failed to indicate the quantity, frequency and strength for the Synapryn. Given the above, the request is not medically necessary.

X-Ray of the Left Wrist: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Forearm, Wrist, & Hand Chapter.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 268-269.

Decision rationale: The California MTUS Guidelines recommend that for most injured workers presenting with true hand and wrist problems, unless there has been a 4 to 6 week period of conservative care and observation. There was a lack of documentation indicating the injured worker had a failure of conservative care specifically directed at the left wrist. The prior diagnostic studies of the left wrist were not provided. Given the above, the request is not medically necessary.

Ketoprofen Cream: 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, Ketoprofen Page(s): 111, 112.

Decision rationale: The California Medical Treatment Utilization Schedule 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. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to provide documentation the injured worker had a trial of antidepressants and anticonvulsants. Additionally, as ketoprofen is not FDA approved for topical application this request would not be supported. The request as submitted failed to indicate the body part, frequency and quantity of medication being requested. Given the above, the request is not medically necessary.

Tabradol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants for pain.

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

Decision rationale: Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization Schedule guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. 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 cyclobenzaprime 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 documented rationale for both a liquid and a topical form of muscle relaxant. There was a lack of documentation indicating the injured worker had an inability to swallow a tablet or capsule. There was a lack of documentation of exceptional factors to warrant non-adherence to recommendations. The request as submitted failed to indicate the quantity, frequency and strength for the requested medication. Given the above, the request is not medically necessary.

Acupuncture for the Cervical Spine and Left Wrist (18-sessions): Upheld

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

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines state that acupuncture is used as an option when pain medication is reduced or not tolerated and it is recommended as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. The time to produce functional improvement is 3-6 treatments and Acupuncture treatments may be extended if functional improvement is documented including either a clinically significant improvement in activities of daily living or a reduction in work restrictions. The clinical documentation submitted for review indicated the injured worker had previously undergone acupuncture therapy. There was a lack of documentation indicating the injured worker had a clinically significant improvement in activities of daily living or a reduction in work restrictions. The quantity of sessions previously attended for the cervical spine and for the left wrist were not noted. There was a lack of documentation of exceptional factors to warrant further treatment without documentation of clinically significant improvement. Therefore, the request is not medically necessary.