MAXIMUS Federal Services

Case Number:	CM15-0011936		
Date Assigned:	01/29/2015	Date of Injury:	01/27/2014
Decision Date:	03/27/2015	UR Denial Date:	01/08/2015
Priority:	Standard	Application Received:	01/20/2015

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, Washington
Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

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 female who reported injury on 01/27/2014. There was a Request for Authorization submitted for review dated 11/25/2014. The mechanism of injury was not provided. The documentation of 11/25/2014 revealed the injured worker had a right wrist surgery with residual pain. The injured worker complained of weakness, numbness, and tingling of the hands and fingers. The injured worker indicated that symptoms persisted but the medications did offer temporary relief of pain and improve her ability to have a restful sleep. On physical examination, the injured worker had mild swelling and well healed surgical scars consistent with prior surgery. There was tenderness to palpation over the carpal bones at the anatomical snuff box. The injured worker had decreased range of motion of the right wrist. The injured worker had sensation to pinprick and light touch that was slightly diminished over the C5-T1 dermatomes in the right upper extremity. Motor strength was decreased secondary to pain in the right upper extremity. The diagnosis included status post right wrist fracture, status post right wrist/hand surgery, rule out right wrist internal derangement, and right wrist/hand sprain/strain. The treatment plan included the injured worker was to continue a course of physical therapy and acupuncture for the right wrist for 3 times a week x6 weeks, continue shockwave therapy up to 3 treatments for the right wrist, and utilize a right wrist cock up brace. The injured worker was currently taking medications including deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, cyclobenzaprine topical gel, and ketoprofen cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen cream 20% 165grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical 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 indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. Additionally, ketoprofen is not FDA approved for topical application. The request as submitted failed to indicate the frequency and the body part to be treated. Given the above, the request for Ketoprofen cream 20% 165grams is not medically necessary.

Cyclobenzaprine cream 5% 100grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics,Cyclobenzaprine Page(s): 111, 41.

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 topical analgesics 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 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. There was a lack of documentation indicating the injured worker had a trial and failure of anticonvulsants and antidepressants. There was a lack of documentation of exceptional factors. There was a lack of documentation indicating a necessity for both an oral and topical form of cyclobenzaprine as this request was concurrently being reviewed in oral form. There was a lack of documented efficacy. The request as submitted failed to indicate the frequency and body part to be treated. Given the above, the request for Cyclobenzaprine cream 5% 100grams is not medically necessary.

Synapryn 10mg/1ml 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 Glucosamine Sulfate, Ongoing Management,Tramadol Page(s): 50, 78, 82, 93, & 94.

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 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 osteoarthritis. The injured worker was noted to be utilizing this medication for an extended duration of time. There is a lack of documentation of objective functional improvement, an objective decrease in pain, and documentation the injured worker was being monitored for aberrant drug behavior and side effects. There was a lack of documentation indicating the injured worker could not swallow tablets or capsules. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Synapryn 10mg/1ml 250ml is not medically necessary.

Tabradol 1mg/ml 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 Chronic pain, 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 cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension. There was a lack of documented efficacy. There was a lack of documentation indicating the frequency for the requested

medication for the submitted request. Additionally, there was a lack of documentation indicating a necessity for both an oral and topical form of the medication. Given the above, the request for Tabradol 1mg/ml 250ml is not medically necessary.

Deprizine 15mg/ml 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, does not specifically address Deprizine, however it does address H-2 Blockers Page(s): 6. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: http://www.drugs.com/search.php?searchterm=Deprizine

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. 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. 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 clinical documentation submitted for review failed to provide the injured worker had dyspepsia. The medication was noted to be a refill, and there was a lack of documented efficacy. There was a lack of documentation indicating the injured worker had an inability to swallow tablets or capsule forms. The request as submitted failed to indicate the frequency for the requested medication. Given the above, and the lack of documentation, the request for Deprizine 15mg/ml 250ml is not medically necessary.

Dicopanol 5mg/5ml 420ml: 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 Chapter, Insomnia Treatments, does not specifically address Dicopanol. 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 indicating the injured worker could not swallow a

tablet or capsule. There was a lack of documentation of efficacy. It was indicated the injured worker could sleep better, however 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 for Dicopanol 5mg/5ml 420ml is not medically necessary.

Fanatrex 25mg/ml 420ml: 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 Chronic pain does not address Fanatrex, Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: http://www.drugs.com/search.php?searchterm=Fanatrex.

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 as the medication has not been approved by the FDA in the form of suspension. The medication was noted to be a refill and there was a lack of efficacy. There was a lack of documentation indicating the tablet was unavailable in tablet or capsule form and the injured worker could not utilize the medication in these forms. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Fanatrex 25mg/ml 420ml is not medically necessary.

Shockwave therapy x 3 for the right wrist: 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 Other Medical Treatment Guideline or Medical Evidence: Wang, Ching-Jen. "Extracorporeal shockwave therapy in musculoskeletaldisorders. 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 indicated the injured worker had previously undergone shockwave therapy. There was a lack of documentation of objective functional benefit that was received, and there was a lack of documentation of exceptional factors to warrant nonadherence to the peer reviewed literature.

Given the above, the request for Shockwave therapy x 3 for the right wrist is not medically necessary.