

Case Number:	CM13-0042824		
Date Assigned:	12/27/2013	Date of Injury:	11/05/2001
Decision Date:	02/13/2014	UR Denial Date:	09/20/2013
Priority:	Standard	Application Received:	10/18/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation 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 physician 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 64 year-old male sustained an injury on 11/5/01 while employed by the District Attorney Office in the County of LA. Requests under consideration include compound Ketoprofen 20% in PLO gel 120 grams, compound Cyclophene 5% in PLO gel 120 grams, Dicopanol 5mg/ml oral suspension 150ml 1ml, Deprizine 5mg/ml oral suspension 250ml 10ml, Fanatrex 25mg/ml oral suspension 420ml 5ml, Synapryn 10mg/1ml oral suspension 500ml 5ml, and Tabradol 1mg/ml oral suspension 250ml 5ml. The diagnoses list degenerative cervical disc; right shoulder pain; bilateral carpal tunnel decompression; wrist deQuervain's tenosynovitis; and s/p left shoulder arthroscopy (date unknown). The report of 8/5/13 from Dr. Johnson noted the patient with complaints of sharp radicular neck pain 3-4/10 intermittent and mild to moderate; bilateral burning shoulder pain 2-4/10 mild to moderate. He is s/p bilateral Carpal tunnel release with residual pain 4-5/10 intermittent mild to moderate. Symptoms persist but the medications offer temporary relief of pain. The exam showed 2+ tenderness at sub occipital and scalene muscles; decreased range with positive distraction; 1+ tenderness at rotator cuff tendon attachment sites/ AC joint and subacromial space; decreased range and positive Neer's impingement sign; 1+tenderness over right carpal tunnel and 2+ tenderness at right first dorsal extensor muscle; positive Tinel's; sensation diminished over median nerve distribution; motor strength decreased secondary to pain. The treatment included acupuncture, MRIs of cervical spine, shoulders and wrists, EMG of upper extremity, shockwave therapy, TENS unit, hot/cold along with above 7 medications. The requests above were non-certified on 9/20/13 citing guidelines criteria and lack of medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound Ketoprofen 20% in PLO gel 120 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 112.

Decision rationale: Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. Monitoring of NSAIDs functional benefit is advised as long term use of NSAIDS beyond a few weeks may actually retard muscle and connective tissue healing. There is no documentation of medical indication of topical agent when the patient is tolerating oral medications. Topical compound analgesics are not recommended by MTUS Guidelines as largely experimental with few randomized control trials to determine its efficacy or safety. Of particular note, Ketoprofen cream is an agent not currently FDA approved for a topical application due to an extremely high incidence of photocontact dermatitis. Per MTUS Chronic Pain Guidelines, the efficacy in clinical trials for topical analgesic treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. There is little evidence to utilize topical compound analgesic over oral NSAIDs or other pain relievers for a patient without contraindication in taking oral medications. There is no information or clarification provided as to what is/are the ingredients for this topical cream and how it is medically necessary to treat this injured worker who is not intolerable to oral medications. Submitted reports have not adequately demonstrated the indication or medical need for this topical compounded analgesic. The compound Ketoprofen 20% in PLO gel 120 grams is not medically necessary and appropriate.

Compound Cyclophene 5% in PLO gel 120 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Section Page(s): 64-65.

Decision rationale: Per MTUS Chronic Pain Guidelines on muscle relaxant, Cyclophene topical is not recommended for mild to moderate chronic persistent pain problems including chronic pain (other than for acute exacerbations) due to the high prevalence of adverse effects in the context of insufficient evidence of benefit as compared to other medications. Submitted reports have no demonstrated spasm or neurological deficits to support for continued use of a muscle relaxant for this 2001 injury. Due to the unchanged objective findings without demonstrated evidence of acute muscle spasm, the indication and necessity for continued use of muscle relaxant has not been adequately addressed to warrant continued treatment regimen. It is also not clear why the patient would require 2 muscle relaxants with two delivery route of topical cream

as with Cyclophene compound cream and oral suspension Tabradol, another cyclobenzaprine. Guidelines do not recommend long-term use of this muscle relaxant for this chronic injury. Additionally, the efficacy in clinical trials for topical analgesic treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. There is little evidence to utilize topical compound analgesic over oral NSAIDs or other pain relievers for a patient without contraindication in taking oral medications. Submitted reports have not demonstrated medical necessity to treat with this topical cream for this injured worker who is not intolerable to oral medications. Submitted reports have not adequately demonstrated the indication or medical need for this topical compounded analgesic. The compound Cyclophene 5% in PLO gel 120 grams is not medically necessary and appropriate

Dicopanol 5mg/ml oral suspension 150ml 1ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Insomnia Treatment

Decision rationale: Dicopanol 5mg/ml oral suspension (Diphenhydramine HCL) is benzodiazepines, not recommended per guidelines for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Submitted documents have not demonstrated any functional improvement from this treatment prescribed for quite some time for this 2001 injury. Dicopanol 5mg/ml oral suspension 150ml 1ml is not medically necessary and appropriate.

Deprizine 5mg/ml oral suspension 250ml 10ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Section Page(s): 68-69.

Decision rationale: Deprizine has active ingredient, Ranitidine, a medication prescribed for treatment of the problems associated with erosive esophagitis from GERD, or in patients with hypersecretion diseases. Per MTUS Chronic Pain Treatment Guidelines, the patient does not meet criteria for Ranitidine namely reserved for patients with history of prior GI bleeding, diabetics, and chronic cigarette smokers. Submitted reports have not described or provided any GI diagnosis that meets the criteria to indicate medical treatment nor any indication that require

medication to be in an oral suspension form. Review of the records show no documentation of any history, symptoms, or GI diagnosis to warrant treatment with this oral suspension. Deprizine 5mg/ml oral suspension 250ml 10ml is not medically necessary and appropriate

Fanatrex 25mg/ml oral suspension 420ml 5ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs/Gabapentin Page(s): 18-19.

Decision rationale: Although, Fanatrex oral suspension which has the active ingredient for the anti-epileptic medication, Gabapentin, has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain; however, submitted reports have not adequately demonstrated the specific indication to support for Fanatrex oral suspension over oral pills. The Fanatrex 25mg/ml oral suspension 420ml 5ml is not medically necessary and appropriate.

Synapryn 10mg/1ml oral suspension 500ml 5ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Page(s): 79.

Decision rationale: Submitted documents show no evidence that the treating physician is prescribing opioids in accordance to change in pain relief, functional goals with demonstrated improvement in daily activities, decreased in medical utilization or returned to work status. MTUS Chronic Pain, page 79-80, states when to continue Opioids, "(a) If the patient has returned to work or (b) If the patient has improved functioning and pain." Regarding when to discontinue opioids, Guidelines state, "If there is no overall improvement in function, unless there are extenuating circumstances." The MTUS provides requirements of the treating physician to assess and document for functional improvement with treatment intervention and maintenance of function that would otherwise deteriorate if not supported. From the submitted reports, there is no demonstrated evidence of specific functional benefit derived from the continuing use of opioids with persistent severe pain. In addition, submitted reports have not adequately demonstrated the specific indication to support for Synapryn oral suspension with active ingredient, Tramadol over oral pills. Synapryn 10mg/1ml oral suspension 500ml 5ml is not medically necessary and appropriate

Tabradol 1mg/ml oral suspension 250ml 5ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant Page(s): 63.

Decision rationale: Per MTUS Chronic Pain Guidelines on muscle relaxant, it is not recommended for mild to moderate chronic persistent pain problems including chronic pain (other than for acute exacerbations) due to the high prevalence of adverse effects in the context of insufficient evidence of benefit as compared to other medications. Submitted reports have no demonstrated spasm or neurological deficits to support for continued use of a muscle relaxant for this 2001 injury. Due to the unchanged objective findings without demonstrated evidence of acute muscle spasm, the indication and necessity for continued use of muscle relaxant has not been adequately addressed to warrant continued treatment regimen. It is also not clear why the patient would require 2 muscle relaxants with two delivery route of topical cream as with Cyclophene compound cream and oral suspension Tabradol, another cyclobenzaprine. MTUS Guidelines do not recommend long-term use of this muscle relaxant for this chronic injury. Tabradol 1mg/ml oral suspension 250ml 5ml is not medically necessary and appropriate.