

<b>Case Number:</b>	CM13-0056338		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	03/31/2006
<b>Decision Date:</b>	05/13/2014	<b>UR Denial Date:</b>	10/28/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/22/2013

### 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 Anesthesiology, Pain Medicine and is licensed to practice in Florida. 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 46-year-old female who reported an injury on 08/01/2004. The mechanism of injury was not provided. The injured worker's medication history included Deprizine, Dicopanlol, Fanatrex, Synapryn, Tabradol, Cyclophene, and ketoprofen topical for greater than 6 months. The prior therapies included physical therapy, chiropractic care, and acupuncture. The documentation of 10/08/2013 revealed the injured worker was status post lumbar spine laminectomy with residual pain and burning sensation. The injured worker indicated the pain was a 7/10 to 8/10. The pain was associated with radiated numbness and tingling of the bilateral lower extremities greater on the left. There was tenderness to palpation over the bilateral PSIS greater on the left and at the lumbar paraspinal muscles. The injured worker had decreased range of motion of the lumbar spine. The injured worker had a positive tripod sign and flip test bilaterally. The sensation to pinprick and light touch was diminished over the L4-S1 dermatomes in the bilateral lower extremities. The injured worker's motor strength was slightly decreased secondary to pain. The diagnoses included status post lumbar spine laminectomy with residual pain, anxiety disorder, and mood disorder. The treatment plan included medication refills, physical therapy, and chiropractic therapy. The request additionally was made for acupuncture.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 PRESCRIPTION OF COMPOUNDED KETOPROFEN 20% IN PLO GEL, 120GM:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Ketoprofen Page(s): 111-112.

**Decision rationale:** California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled 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. Regarding the use of Ketoprofen, this agent is not currently FDA approved for a topical application. The clinical documentation submitted for review indicated the injured worker had been taking the medication for greater than 6 months. There was lack of documentation of the efficacy of the requested medication. The submitted request failed to indicate the frequency for the medication. Given that guidelines do not recommend ketoprofen, the request for 1 prescription of compounded ketoprofen 20% in PLO gel 120 grams is not medically necessary.

**1 PRESCRIPTION OF COMPOUNDED CYCLOPHENE 5% PLO GEL, 120GM:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Topical Muscle Relaxants; Cyclobenzaprine Page(s): 111-113, 41.

**Decision rationale:** California MTUS indicates topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and 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. California MTUS Guidelines do not recommend the topical use of cyclobenzaprine as 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 indicated the injured worker had been utilizing the compounded product for greater than 6 months. There was lack of documentation indicating the efficacy of the requested medication. There was lack of documentation indicating necessity for both a topical and oral form of cyclobenzaprine. The request as submitted failed to indicate the frequency for the medication. Given the above, the request for 1 prescription of compounded Cyclophene 5% PLO gel 120 grams is not medically necessary.

**RETROSPECTIVE REQUEST FOR 1 PRESCRIPTION OF SYNAPRYN 10MG/1ML ORAL SUSPENSION, #250:** 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:** 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 taking the medication for greater than 6 months. There was lack of documentation indicating the injured worker had inability to swallow or tolerate pills. There was lack of documentation of an objective decrease in pain and an improvement in function. The request as submitted failed to indicate the frequency for the medication. Given the above, the request for retrospective request for 1 prescription of Synapryn 10mg/1mL oral suspension, #250 is not medically necessary.

### **1 PRESCRIPTION OF TABRADOL 1MG/ML ORAL SUSPENSION, #250: 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 Cyclobenzprine Page(s): 41.

**Decision rationale:** 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 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. A search of ACOEM, California MTUS 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 of these medications. The clinical documentation submitted for review indicated the injured worker had been on the

medication for greater than 6 months. There was lack of documentation indicating the injured worker had inability to swallow or tolerate a pill. There was lack of documentation indicating the necessity for 2 forms of cyclobenzaprine. This medication was concurrently being reviewed for a topical form. The request as submitted failed to indicate the frequency for the medication. Given the above, the request for 1 prescription of Tabradol 1 mg/mL oral suspension #250 is not medically necessary.

**RETROSPECTIVE REQUEST FOR 1 PRESCRIPTION OF DEPRIZINE 15MG/ML ORAL SUSPENSION #250: 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 NSAID Page(s): 69.

**Decision rationale:** 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 indicated the injured worker had been taking the medication for greater than 6 months. There was lack of documentation indicating the injured worker had necessity for a liquid form of an H2 blocker. Given the above and the lack of documented efficacy, the retrospective request for 1 prescription of Deprizine 50 mg/mL oral suspension is not medically necessary. The request as submitted failed to indicate the frequency.

**RETROSPECTIVE REQUEST FOR 1 PRESCRIPTION OF DICOPANOL 5MG/ML ORAL SUSPENSION #150: 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: <http://www.drugs.com/search.php?searchterm=Dicopanол>

**Decision rationale:** Per Drugs.com, Dicopanол 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 submitted for review indicated the injured worker had been utilizing the medication for greater than 6 months. There was lack of documentation indicating the injured

worker had inability to swallow or tolerate a pill. There was lack of documented efficacy. The request as submitted failed to indicate the frequency. Given the above, the retrospective request for 1 prescription of Dicopanol 5 mg/mL oral suspension #150 is not medically necessary.

### **1 PRESCRIPTION OF FANATREX 25MG/ML ORAL SUSPENSION 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 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:** 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 failed to indicate the frequency for the medication. There was lack of documentation indicating the efficacy of the requested medication as the injured worker had been on the medication for greater than 6 months. There was lack of documentation of exceptional factors to warrant non-adherence to FDA regulations and guideline regulations. Given the above, the request for 1 prescription of Fanatrex 25 mg/mL oral suspension 420 mL is not medically necessary.

### **18 ACUPUNCTURE VISITS THREE TIMES A WEEK FOR SIX WEEKS: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** California MTUS 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. The time to produce functional improvement is 3 to 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 utilized acupuncture. However, there was lack of documentation indicating the quantity of sessions and that the injured worker had significant functional improvement. The request as submitted failed to indicate the body part to be treated. Given the above, the request for acupuncture visits 3 times a week for 6 weeks is not medically necessary.

**Chiropractic Treatment: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy Page(s): 58-59.

**Decision rationale:** California MTUS states that manual therapy and manipulation is recommended for chronic pain if caused by musculoskeletal conditions. For the low back, therapy is recommended initially in a therapeutic trial of 6 sessions and with objective functional improvement a total of up to 18 visits over 6 to 8 weeks may be appropriate. Treatment for flare-ups requires a need for re-evaluation of prior treatment success. Treatment is not recommended for the ankle & foot, carpal tunnel syndrome, the forearm, wrist, & hand or the knee. Treatment beyond 4 to 6 visits should be documented with objective improvement in function. The maximum duration is 8 weeks and at 8 weeks patients should be re-evaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. The clinical documentation submitted for review indicated the injured worker had previously participated in chiropractic treatment. There was lack of documentation indicating the quantity of sessions that had been utilized and the body part that had been treated. There was lack of documentation of objective functional improvement. There was lack of documentation of decrease in pain. The request as submitted failed to indicate the quantity of sessions being requested, as well as the body part to be treated. Given the above, the request for chiropractic treatment is not medically necessary.

**18 PHYSICAL THERAPY SESSIONS THREE TIMES A WEEK FOR SIX WEEKS:**  
Upheld

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

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

**Decision rationale:** California MTUS Guidelines indicate physical medicine treatment is recommended for a maximum of 9 to 10 visits for myalgia and myositis. The clinical documentation submitted for review failed to indicate the quantity of physical therapy sessions the injured worker participated in. There was lack of documentation indicating the functional benefit that was received from the prior physical therapy sessions. There was lack of documentation indicating the functional deficits that remained to support the necessity for physical therapy. The request as submitted failed to indicate the body part to be treated. The request would be excessive. Given the above, the request for 8 physical therapy sessions 3 times a week for 6 weeks is not medically necessary.

**1 FOLLOW UP APPOINTMENT WITH SECONDARY PHYSICIAN** [REDACTED]

[REDACTED] Overturned

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Chapter, office visits

**Decision rationale:** Official Disability Guidelines indicate the need for an office visit with a healthcare provider is individualized based upon review of the patient's concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The clinical documentation submitted for review indicated the injured worker was being treated by the physician indicated in the request. The injured worker was noted to having continued symptoms and objective examination findings. Given the above, the request for 1 follow-up appointment with secondary physician, [REDACTED], is medically necessary.