

<b>Case Number:</b>	CM14-0219224		
<b>Date Assigned:</b>	02/05/2015	<b>Date of Injury:</b>	04/07/2004
<b>Decision Date:</b>	03/30/2015	<b>UR Denial Date:</b>	12/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/31/2014

### 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. 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, Arizona

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 55-year-old male who reported an injury on 04/07/2004. The mechanism of injury was repetitive motion. The injured worker was noted to undergo right hand carpal tunnel release and right shoulder arthroscopy. Therapy included physical therapy. Other treatments included platelet rich plasma injections into the shoulder. There was a Request for Authorization submitted for review dated 12/03/2014. The documentation of 12/03/2014 revealed the injured worker had complaints of burning, radicular pain, and muscle spasms in the cervical spine, pain in the bilateral shoulders including burning and radiation down to the fingers and arms, bilateral wrist pain and muscle spasms, and burning radicular low back pain and muscle spasms. The injured worker indicated the medications offered temporary relief and improved his ability to have a restful sleep. The injured worker denied side effects. On physical examination, the injured worker had tenderness to palpation in the suboccipital region, trapezius and scalene muscles. The injured worker had decreased range of motion of the cervical spine. The injured worker had tenderness to palpation in the subacromial space and the supraspinatus tendon of the bilateral shoulders. The injured worker had decreased range of motion of the bilateral shoulders. The injured worker had a positive Neer's impingement sign bilaterally. The injured worker had tenderness to palpation over the carpal bones and thenar eminence of the bilateral wrists and decreased range of motion of the wrists in flexion, extension, and ulnar deviation. The injured worker had a positive Tinel's at the bilateral wrists. The injured worker had decreased range of motion of the lumbar spine. Sensation to pinprick and light touch was intact. Motor strength was reduced secondary to pain. The diagnoses included cervicalgia,

cervical radiculopathy, bilateral shoulder internal derangement, bilateral wrist tenosynovitis, lumbago, and lumbar radiculopathy. The treatment plan included a periodic urinalysis toxicology evaluation, consultation with a pain management specialist regarding epidural steroid injections for the cervical and lumbar spine, a continuation of PRP treatments for the right shoulder for functional improvement, Terocin patches for pain relief, Dicopanol, Deprizine, Fanatrex, Synapryn, Tabradol, and a return appointment. The documentation indicated the injured worker had utilized the requested medications since at least 07/2014.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Pain management consultation:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Introduction Page(s): 1.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines recommend upon ruling out a potentially serious condition, conservative management is provided. If the complaint persists, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary. The clinical documentation submitted for review indicated the request was made for the injured worker to have an evaluation for epidural steroid injections. However, there was a lack of documentation of objective findings to support the necessity for epidural steroid injections in the lumbar spine. The documentation indicated sensation to pinprick was intact over C5-T1 dermatomes in the bilateral upper extremities. The myotomes were decreased secondary to pain. The lumbar spine examination revealed a positive straight leg raise at 45 degrees; however, there was a lack of documentation of radiating pain with the straight leg raise. Additionally, the sensory and motor extremity evaluation were within normal limits. This request would not be supported. Given the above, the request for pain management consultation is not medically necessary.

**Fanatrex 25mg/ml #420ml:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 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 indicate the injured worker had an inability to swallow or tolerate a pill. The efficacy of the medication was not provided including a relief of pain and objective functional improvement. 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.

**Dicopanol 5mg/ml 150ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Mental Illness & Stress

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Insomnia Treatments, does not specifically address 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 exceptional factors. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The efficacy of the medication was not provided including a relief of pain and objective functional improvement. The request as submitted failed to indicate the frequency for the requested medication. Given the above, request for Dicopanol 5mg/ml 150ml is not medically necessary.

**Deprizine 15mg/ml #250ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System, Academic Institution

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines NSAIDS, does not specifically address Deprizine, however it does address H-2 Blockers. 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. 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 provide documentation of exceptional factors. There was a lack of documentation indicating the injured worker's condition created an inability to swallow or tolerate a pill. The efficacy of the medication was not provided including a relief of pain and objective functional improvement. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Deprizine 15mg/ml #250ml is not medically necessary.

**Tabradol 1mg/ml #250ml:** 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 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 of these medications. The clinical documentation submitted for review failed to provide exceptional factors. The efficacy of the medication was not provided including a relief of pain and objective functional improvement. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Tabradol 1mg/ml #250 is not medically necessary.

**Synapryn 10mg/ml #500ml:** Upheld

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

**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 Other Medical Treatment Guideline or Medical Evidence: 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 indicate the injured worker had no side effects. There was a lack of documentation of objective functional improvement and an objective decrease in pain. There was documentation the injured worker was being monitored for aberrant drug behavior through urine drug screens. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Synapryn 10mg/ml #500ml is not medically necessary.

**Platelet rich plasma therapy: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Shoulder (Acute & Chronic)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Shoulder Chapter, Platelet-rich plasma (PRP).

**Decision rationale:** The Official Disability Guidelines indicate that platelet rich plasma is understudy as a solo treatment; however, it is recommended in conjunction with arthroscopic repair for large or massive rotator cuff tears. The clinical documentation submitted for review indicated the injured worker had undergone platelet rich plasma therapy. There was a lack of documentation of objective functional benefit that was received and exceptional factors to support continuance of the therapy. The request as submitted failed to indicate the body part to be treated with the platelet rich plasma. Given the above and the lack of documentation, including the quantity of sessions and the body part to be treated, the request for platelet rich plasma therapy is not medically necessary.

**Unknown prescription of Terocin patches: Upheld**

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

**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 Other Medical Treatment Guideline or Medical Evidence:  
<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>.

**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](http://dailymed.nlm.nih.gov), Terocin patches are topical Lidocaine and Menthol. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of an antidepressant and an anticonvulsant. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The efficacy of the medication was not provided. The request as submitted failed to indicate the quantity of medication and the body part to be treated, as well as the frequency. Given the above, the request for an unknown prescription of Terocin patches is not medically necessary.