

<b>Case Number:</b>	CM15-0011991		
<b>Date Assigned:</b>	02/13/2015	<b>Date of Injury:</b>	02/13/2012
<b>Decision Date:</b>	05/22/2015	<b>UR Denial Date:</b>	12/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/21/2015

### 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: 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 31 year old male, who sustained an industrial injury on 2/13/2012. He reported left hand pain. The injured worker was diagnosed as having status post left hand surgery, bilateral hand sprain/strain, lumbar spine sprain/strain, and lower extremity radiculitis. Treatment to date has included medications, left hand surgery, and occupational therapy. The request is for Ketoprofen 20% cream 165 grams, Cyclobenzaprine 5% cream 100 grams, Synapryn 10mg/ml oral suspension 500ml, Tabradol 1ml/ml oral suspension 250ml, Dicopanol (Diphenhydramine) 5mg/ml oral suspension #150ml, Fanatrex (Gabapentin) 25mg/ml oral suspension #420ml, Deprizine 15ml/ml oral suspension 250ml, Terocin patches, chiropractic sessions, physical therapy, and acupuncture. On 11/24/2014, he reported residual left hand pain. He reported having right hand pain. He rated his pain level as 5/10. He also reported having low back pain he rated as 7/10 on a pain scale. The records indicate he has undergone surgery of the left hand, and reported that his current medications provide him temporary relief of the continued pain. The treatment plan included: the requested medications, physical therapy, chiropractic treatment, and acupuncture.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% cream, 165 grams: 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 Page(s): 111-114.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs, such as ketoprofen are recommended for the treatment of osteoarthritis and tendonitis in joints that lend themselves to treatment. The documentation provided fails to show that the injured worker has tried and failed recommended oral medications to support the request for topical analgesic. Also, his response to this medication in terms of quantitative decrease in pain or an objective improvement in function were not clearly stated within the report. Also, the frequency of the medication was not stated within the request. Therefore, the request is not supported. As such, the request is not medically necessary.

**Cyclobenzaprine 5% cream, 100 grams:** 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 Page(s): 111-114.

**Decision rationale:** The California MTUS Guidelines indicate that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical Cyclobenzaprine is not recommended for use as there is little peer reviewed literature to support its use of the topical analgesic. Therefore, the compound cream requested would not be supported. Also, the frequency of the medication was not stated within the request and there is a lack of documentation showing that the injured worker has tried and failed recommended oral medications. Therefore, the request is not supported. As such, the request is not medically necessary.

**Synapryn 10mg/ml oral suspension, 500ml:** 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, Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94.

**Decision rationale:** The California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. 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. Clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. There was no indication that the injured worker had the inability to swallow or tolerate a pill. Therefore, the request is not supported. As such, the request is not medically necessary.

**Tabradol 1mg/ml oral suspension, 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 Cyclobenzaprine 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 a 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. There was no indication that the injured worker had the inability to swallow or tolerate a pill. Therefore, the request is not supported. As such, the request is not medically necessary.

**Dicopanol (Diphenhydramine) 5mg/ml oral suspension, 150ml: 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, Insomnia treatment 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, Dicopanil 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. There was no indication that the injured worker had the inability to swallow or tolerate a pill. Therefore, the request is not supported. As such, the request is not medically necessary.

**Fanatrex (Gabapentin) 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 rationale:** The 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. Given the above, and the lack of documentation of exceptional factors to warrant non-adherence to FDA guidelines, the request for prescription for Fanatrex is not medically necessary.

**Deprizine 15mg/ml oral suspension, 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/GI Risks Page(s): 68-69.

**Decision rationale:** California MTUS 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. There was no indication that the injured worker had the inability to swallow or tolerate a pill. Therefore, the request is not supported. As such, the request 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 Topical Analgesics Page(s): 111-114.

**Decision rationale:** The California MTUS Guidelines indicate that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The documentation submitted for review does not show that the injured worker has tried and failed recommended oral medications to support the medical necessity of this request. Also, the frequency of this medication was not stated within the request nor was the dosage or quantity. Therefore, the request is not supported. As such, the request is not medically necessary.

**18 sessions of chiropractic:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy and manipulation.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy and Manipulation Page(s): 58.

**Decision rationale:** The California MTUS Guidelines indicate that chiropractic therapy is recommended for musculoskeletal pain. The documentation submitted for review does not show that the injured worker has any significant functional deficits that would support the request for chiropractic therapy. Also, the number of sessions being requested is excessive and would not be supported. Furthermore, the body part to receive chiropractic therapy was not stated within the request. Therefore, the request is not supported. As such, the request is not medically necessary.

**18 sessions of physical therapy:** 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 indicate that physical therapy is recommended for 9 to 10 visits over 8 weeks for myalgia and myositis unspecified. For neuralgia, neuritis and radiculitis unspecified, 8 to 10 visits over 4 weeks is recommended. The documentation submitted for review does not show that the injured worker has any significant functional deficits that would support the request for chiropractic therapy. Also, the number of sessions being requested is excessive and would not be supported. Furthermore, the body part to receive physical therapy was not stated within the request. Therefore, the request is not supported. As such, the request is not medically necessary.

**18 sessions of acupuncture:** Upheld

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

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

**Decision rationale:** The California Acupuncture Treatment Guidelines indicate that acupuncture is used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery and can also be used when medications are decreased or not tolerated well. The documentation submitted for review does not show that the injured worker has any significant functional deficits that would support the request for chiropractic therapy. Also, the number of sessions being requested is excessive and would not be supported. Furthermore, the body part to receive acupuncture was not stated within the request. Therefore, the request is not supported. As such, the request is not medically necessary.