

<b>Case Number:</b>	CM13-0023398		
<b>Date Assigned:</b>	11/15/2013	<b>Date of Injury:</b>	09/15/2010
<b>Decision Date:</b>	04/14/2014	<b>UR Denial Date:</b>	09/03/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/12/2013

### 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 Orthopedic Surgery and Hand Surgery, and is licensed to practice in Texas. 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:

The patient is a 29-year-old female who reported injury on 09/15/2010. The mechanism of injury was not provided. The documentation indicated the patient had been taking the medications since 12/2012. The patient indicated that the medications helped the patient sleep 6 hours per night. The patient was noted to have continuing pain in multiple parts of her body. The pain was rated from 3/10 to 8/10. The physical examination revealed the patient had tingling of the right hand with repetitive use and nonspecific tenderness in the right hand. The patient's grip strength with the Jamar dynamometer was decreased on the right compared to the left. The patient had nonspecific tenderness to palpation in the right shoulder with a slight tenderness at the supraspinatus and infraspinatus on the right. The patient was noted to have pain with the supraspinatus resistance test, Speed's bicipital tendonitis and impingement maneuver as well as Yerguson's sign. The patient had impingement of the right shoulder. However, the patient's range of motion of the bilateral shoulders were within normal limits. Palpation of the right elbow revealed nonspecific tenderness. The patient had medial and lateral epicondyle tenderness on the right elbow. The patient had nonspecific tenderness at the right elbow. The patient had a positive Phalen's and Tinel's on the right wrist as well as a Finkelstein's test that revealed pain on the right wrist. The patient's diagnoses were noted to include right sprain of infraspinatus tendon of the shoulder per the MRI 05/13/2011 and right carpal tunnel syndrome per MRI of 05/13/2011 as well as unspecified sleep disturbance. The request was made for medication refills, referral for a specialist for the right arm and a followup appointment.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 REQUEST FOR COMPOUNDED KETOPROFEN 20% IN PLO GEL 120 GRAMS BETWEEN 7/29/13 AND 10/13/13: Upheld**

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

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

**Decision rationale:** The MTUS guidelines indicate that 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 failed to provide documentation of exceptional factors to warrant nonadherence to FDA and guideline recommendations. There was a lack of documentation indicating the employee had trialed and failed antidepressants and anticonvulsants. The employee was noted to be taking the medication since 2012. There was a lack of documentation of the efficacy of the requested medication. Given the above, the request for 1 request for compounded ketoprofen 20% in PLO gel 120 grams between 7/29/13 and 10/13/13 is not medically necessary.

**1 REQUEST FOR PRESCRIPTION OF SYNAPRYN 10MG/1ML ORAL SUSPENSION 500ML BETWEEN 7/29/13 AND 10/13/13: 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 Section Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 83, 93, 94. Decision based on Non-MTUS Citation Synapryn online drug insert, FDA.gov (website).

**Decision rationale:** The 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. The 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, according to 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. The MTUS guidelines also indicate there should be documentation of the patient's analgesia, activities of daily living, adverse side effects and that the patient is being monitored for aberrant drug taking behavior. The MTUS guidelines indicate 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 failed to provide documentation of exceptional factors to warrant nonadherence to FDA and guidelines recommendations. There was a lack of documentation indicating the employee had trialed and failed antidepressants and anticonvulsants. The employee was noted to be taking the medication since 2012. There was a lack of documentation of the efficacy of the requested medication. Given the above, the request for 1 REQUEST FOR PRESCRIPTION OF SYNAPRYN 10MG/1ML ORAL SUSPENSION 500ML BETWEEN 7/29/13 AND 10/13/13 is not medically necessary.

**1 REQUEST FOR PRESCRIPTION OF TABRADOL 1MG/ML ORAL SUSPENSION 250ML BETWEEN 7/29/13 AND 10/13/13: 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 Section Cyclobenzaprine Page(s): 41.

**Decision rationale:** The MTUS guidelines 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. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. Given the 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, Tabradol is not medically necessary. The MTUS guidelines indicate 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 failed to provide documentation of exceptional factors to warrant nonadherence to FDA and guidelines recommendations. There was a lack of documentation indicating the employee had trialed and failed antidepressants and anticonvulsants. The employee was noted to be taking the medication since 2012. There was a lack of documentation of the efficacy of the requested medication. Given the above, the request for 1 REQUEST FOR PRESCRIPTION OF TABRADOL 1MG/ML ORAL SUSPENSION 250ML BETWEEN 7/29/13 AND 10/13/13 is not medically necessary.

**1 REQUEST FOR PRESCRIPTION OF DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML BETWEEN 7/29/13 AND 10/13/13: 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 Section NSAIDs Page(s): 69.

**Decision rationale:** The MTUS Guidelines recommend 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 clinical documentation submitted for review failed to indicate the employee had signs and symptoms of dyspepsia. The employee had been noted to be on the medication since 2012. There was a lack of documentation indicating the efficacy of the requested medication. Given the above, the request for 1 REQUEST FOR PRESCRIPTION OF DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML BETWEEN 7/29/13 AND 10/13/13 is not medically necessary.

**1 REQUEST FOR PRESCRIPTION OF DICOPANOL 5MG/ML ORAL SUSPENSION 150ML BETWEEN 7/29/13 AND 10/13/13: 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  
<http://www.drugs.com/search.php?searchterm=Dicopanol>

**Decision rationale:** According to 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 clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. The MTUS guidelines indicate 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 failed to provide documentation of exceptional factors to warrant nonadherence to FDA and guidelines recommendations. There was a lack of documentation indicating the employee had trialed and failed antidepressants and anticonvulsants. The employee was noted to be taking the medication since 2012. There was a lack of documentation of the efficacy of the requested medication. Given the above, the request for 1 REQUEST FOR PRESCRIPTION OF DICOPANOL 5MG/ML ORAL SUSPENSION 150ML BETWEEN 7/29/13 AND 10/13/13 is not medically necessary.

**1 REQUEST FOR PRESCRIPTION OF FANATREX 25MG/ML ORAL SUSPENSION 420 ML BETWEEN 7/29/13 AND 10/13/13: 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 Section Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Website <http://www.drugs.com/search.php?searchterm=Fanatrex>.

**Decision rationale:** The MTUS guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. According to drugs.com, Fanatrex is an oral suspension of Gabapentin and has not been found to be FDA-safe and effective, and the labeling has not been approved by the FDA. 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. The MTUS guidelines indicate 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 failed to provide documentation of exceptional factors to warrant nonadherence to FDA and guidelines recommendations. There was a lack of documentation indicating the employee had trialed and failed antidepressants and anticonvulsants. The employee was noted to be taking the medication since 2012. There was a lack of documentation of the efficacy of the requested medication. Given the above, the request for 1 REQUEST FOR PRESCRIPTION OF FANATREX 25MG/ML ORAL SUSPENSION 420 ML BETWEEN 7/29/13 AND 10/13/13 is not medically necessary.

**1 REQUEST FOR CONSULT WITH AN ORTHOPEDIC SURGEON BETWEEN 7/29/13 AND 10/13/13:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 254.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 209-210.

**Decision rationale:** The ACOEM Guidelines indicate a referral for surgical consultation may be indicated for patients who have red flag conditions, activity limitation for more than 4 months plus the existence of a surgical lesion, failure to increase range of motion and strength of the musculature around the shoulder even after exercise programs plus existence of a surgical lesion and imaging evidence of a lesion that has been shown to benefit in both the short and long-term from surgical repair. Clinical documentation submitted for review indicated the employee had an MRI; however, there was lack of documentation indicating the official read for the MRI. Additionally, the request as submitted failed to indicate the type of consultation that was being requested. Given the above the consideration for 1 request for consult with an orthopedic surgeon between 07/29/2013 and 10/13/2013 was not medically necessary.

### **1 FOLLOW-UP APPOINTMENT BETWEEN 7/29/13 AND 10/13/13: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 207.

**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, Office Visits.

**Decision rationale:** The Official Disability Guidelines indicate that the need for a clinical office visit with a healthcare provider is individualized based upon a review of the patient's concerns, signs and symptoms, clinical stability and reasonable physician judgment. The request as submitted failed to indicate the type of follow-up appointment that was being requested. Given the above, the request for 1 follow-up appointment between 07/29/2013 and 10/13/2013 was not medically necessary.

### **1 REQUEST FOR PERIODIC URINALYSIS (UA) TOXICOLOGICAL EVALUATION BETWEEN 7/29/13 AND 10/13/13: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Opiates, steps to avoid misuse/addiction.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids, On-Going Management Page(s): 78.

**Decision rationale:** The MTUS guidelines indicate that the use of urine drug screening is for patients with documented issues of abuse, addiction, or poor pain control. The clinical documentation submitted for review failed to indicate the employee had documented issues of abuse, addiction, or poor pain control. Given the above, the consideration for 1 request for periodic urinalysis toxicology evaluation between 07/29/2013 and 10/13/2013 is not medically necessary.

### **1 REQUEST FOR PRESCRIPTION OF CYCLOPHENE 5% IN PLO GEL 120 GRAMS BETWEEN 7/29/13 AND 10/13/13: 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 Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances, pg. 33.

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

**Decision rationale:** The MTUS guidelines indicate 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. The MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any muscle relaxant as a topical product. The MTUS guidelines indicate 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 failed to provide documentation of exceptional factors to warrant nonadherence to FDA and guidelines recommendations. There was a lack of documentation indicating the employee had trialed and failed antidepressants and anticonvulsants. The employee was noted to be taking the medication since 2012. There was a lack of documentation of the efficacy of the requested medication. Given the above, the request for 1 REQUEST FOR PRESCRIPTION OF CYCLOPHENE 5% IN PLO GEL 120 GRAMS BETWEEN 7/29/13 AND 10/13/13 is not medically necessary.