

Case Number:	CM14-0021838		
Date Assigned:	05/12/2014	Date of Injury:	11/14/2012
Decision Date:	07/23/2014	UR Denial Date:	01/15/2014
Priority:	Standard	Application Received:	02/21/2014

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. The expert reviewer is Board Certified in Occupational Medicine, 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 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 patient is a 25-year-old male who has filed a claim for laceration and fracture of the right hand 5th finger associated with an industrial injury date of November 14, 2012. Review of progress notes indicates right wrist and hand pain radiating up to the elbow, associated with numbness, tingling, and weakness of the hand and fingers. Findings include tenderness over the triangular fibrocartilage complex and carpal tunnel, a trigger point at the carpal tunnel, positive Tinel's and Phalen's signs, decreased grip strength, decreased sensation of along the median nerve distribution, decreased muscle strength of the right upper extremity, and contracture of the small finger with trembling of the flexor digitorum profundus. Treatment to date has included NSAIDs, compounded topicals, Synapryn, Deprizine, Fanatrex, shockwave therapy, and surgery to the 5th finger of the right hand. Utilization review from January 15, 2014 denied the requests for compounded cyclophene and ketoprofen, and Tabradol, as they are not supported for topical application; Synapryn as it is not approved by FDA, and there is no indication why an oral suspension is needed; Deprizine as there is no documentation of GI disorders, and no rationale for an oral suspension; and Fanatrex as there is no rationale for an oral suspension.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUNDED KETOPROFEN 20% IN PLO GEL120 GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: As noted on pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen is not currently FDA-approved for topical application. It has an extremely high incidence of photo contact dermatitis. Patient has been on this medication since at least June 2013. There is no documentation regarding intolerance to or failure of first-line pain medications. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for compounded Ketoprofen 20% in PLO gel 120g was not medically necessary.

COMPOUNDED CYCLOPHENE 5% IN PLO GEL 120 GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

Decision rationale: Cyclophene contains cyclobenzaprine hydrochloride and other proprietary ingredients. As noted on page 112-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. Patient has been on this medication since at least June 2013. There is no documentation regarding intolerance to or failure of first-line pain medications. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for compounded cyclophene 5% gel was not medically necessary.

SYNAPRYN 10 MG/1 ML SUSPENSION 500 ML: 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: Synapryn <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=20039>.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. A search of online resources revealed that Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. Additionally, this drug has not been found by FDA to be safe and effective, and is not approved by the FDA. Patient has been on this medication since at least June 2013. There is no

documentation regarding intolerance to or failure of first-line pain medications. Furthermore, there is no clear rationale identifying why a compound/oral suspension (as opposed to the evidence based guidelines supported and FDA approved non-compounded medication) is needed for this patient. Therefore, the request for Synapryn 10mg/1ml suspension 500ml was not medically necessary.

TABRADOL 1 MG/ML ORAL SUSPENSION 250 ML: 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 Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Tabradol
<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

Decision rationale: Tabradol is cyclobenzaprine hydrochloride with MSM in oral suspension. CA MTUS Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. Patient has been on this medication since at least June 2013. There is no documentation regarding intolerance to or failure of first-line pain medications. In addition, Methylsulfonylmethane (MSM) is not FDA approved. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for Tabradol 1mg/ml oral suspension 250ml was not medically necessary.

DEPRIZINE 15 MG/ML ORAL SUSPENSION 250 ML: 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: Depirizine <http://www.drugs.com/pro/deprizine.html>.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. According to FDA, Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. There is no documentation regarding upper GI symptoms in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Deprizine 15mg/ml oral suspension 250ml was not medically necessary.

FANATREX (GABAPENTIN) 25 MG/ML ORAL SUSPENSION 420 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-18.

Decision rationale: Page 16 of CA MTUS Chronic Pain Medical Treatment Guidelines states that gabapentin is used to treat diabetic painful neuropathy and postherpetic neuralgia. Fanatrex is gabapentin with other proprietary ingredients in oral suspension. However, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml was not medically necessary.