

<b>Case Number:</b>	CM13-0056842		
<b>Date Assigned:</b>	06/09/2014	<b>Date of Injury:</b>	06/24/2011
<b>Decision Date:</b>	12/11/2014	<b>UR Denial Date:</b>	11/15/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/23/2013

### 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, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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:

Patient is a 50-year-old female who has submitted a claim for cervical disc displacement, cervical spine radiculopathy, lumbar intervertebral disk displacement, lumbar radiculopathy, and unspecified internal derangement of bilateral knees associated with an industrial injury date of 6/24/2011. Medical records from 2014 were reviewed. The patient complained of burning, radicular neck pain and muscle spasms, rated 8/10 in severity. Patient likewise experienced low back pain associated with numbness and tingling sensation to bilateral lower extremities. Patient reported that intake of medications provided temporary pain relief and allowed her to have a restful sleep. She denied any problems with her medications. Physical examination of the cervical spine showed tenderness, limited motion, positive Spurling's test, and positive compression test. Weakness and diminished sensation were noted at the bilateral upper and lower extremities. Examination of the lumbar spine showed tenderness, restricted motion, positive straight leg raise test at 30 degrees bilaterally, and positive Kemp's test. Crepitation was noted at both knees. Tenderness, effusion, and limited motion were also noted. Treatment to date has included left suprascapular nerve block, left shoulder mobilization, acupuncture, physical therapy, chiropractic care, and medications such as Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, and compounded creams (since 2013). Utilization review from 11/15/2013 denied the requests for compounded ketoprofen 20% in plo gel, 120 gms and compounded Cyclophene 5% in plo gel, 120 gms, Tabradol 1mg/ml 250ml, Deprizine 15mg/ml 250ml, and Dicopanol 5mg/ml 150ml. The request for Synapryn 10mg/1 ml 500 ml was modified into tramadol oral capsules, 50 mg t.i.d. p.r.n. while Fanatrex 25mg/ml 420ml was also modified into Fanatrex 25mg/ml for a one-month supply, and then transitioned to capsules.

### 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 GEL, 120 GMS: 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): 111-113.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Ketoprofen is not recommended for topical use as there is a high incidence of photo contact dermatitis. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains ketoprofen, which is not recommended for topical use. It is unclear why oral medications cannot suffice. There is no evidence of intolerance to or failure of oral formulations to warrant topical use. The medical necessity cannot be established due to insufficient information. Therefore, the request for compounded ketoprofen 20% in plo gel, 120 gms is not medically necessary.

**COMPOUNDED CYCLOPHENE 5% IN PLO GEL, 120 GMS: 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): 111-113.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Cyclobenzaprine is not recommended for use as a topical analgesic. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains cyclobenzaprine, which is not recommended for topical use. It is unclear why oral medications cannot suffice. There is no evidence of intolerance to or failure of oral formulations to warrant topical use. The medical necessity cannot be established due to insufficient information. Therefore, the request for compounded Cyclophene 5% in plo gel, 120 gms is not medically necessary.

**SYNAPRYN 10MG/1 ML 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: US Food and Drug Administration, Synapryn

**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. In this case, Synapryn was prescribed since 2013. However, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, there is no data concerning previous drugs that the patient had tried and failed leading to prescription of oral suspension medications. Lastly, the requested drug is generally not recommended as stated above. Therefore, the request for Synapryn 10 mg/1ml oral suspension 500 ml is not medically necessary.

**TABRADOL 1MG/ML 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 (Flexeril) Page(s): 41-42. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: US Food and Drug Administration, Tabradol

**Decision rationale:** Tabradol is cyclobenzaprine hydrochloride with MSM in oral suspension. CA MTUS Chronic Pain Medical Treatment Guidelines state that cyclobenzaprine is a skeletal muscle relaxant and a CNS depressant that is recommended as a short-course therapy. The effect is greatest in the first 4 days of treatment. In this case, patient has been on Tabradol suspension since 2013. However, there is no documentation regarding intolerance to cyclobenzaprine in tablet form. 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 250 ml is not medically necessary.

**DEPRIZINE 15MG/ML 250ML:** 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: US Food and Drug Administration, Deprizine

**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. In this case, patient has been on Deprizine since 2013. However, patient has no subjective complaints or objective findings pertaining to the gastrointestinal system that may

warrant prescription of such. Moreover, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Deprizine 15mg/ml oral suspension 250 mL is not medically necessary.

**DICOPANOL 5MG/ML 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 Other Medical Treatment Guideline or Medical Evidence: US Food and Drug Administration, Dicopanol

**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. Dicopanol is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. In this case, patient has been on Dicopanol since 2013. However, there is no evidence of insomnia based on the medical records submitted. Moreover, there is no discussion concerning sleep hygiene and if non-pharmacologic management has been attempted first. Therefore, the request for Dicopanol diphenhydramine 5mg/ml oral suspension 150 ml is not medically necessary.

**FANATREX 25MG/ML 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 Antiepilepsy drugs (AEDs) Page(s): 16-18.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that Fanatrex is gabapentin with other proprietary ingredients in oral suspension. Gabapentin is used to treat diabetic painful neuropathy and postherpetic neuralgia. In this case, patient has been on Fanatrex since 2013 for neuropathic pain. However, there is no documentation concerning pain relief and functional improvement derived from its use. There is likewise no rationale provided for the medical necessity of an oral suspension. The medical necessity cannot be established due to insufficient information. Therefore, the request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml is not medically necessary.