

<b>Case Number:</b>	CM13-0027322		
<b>Date Assigned:</b>	03/14/2014	<b>Date of Injury:</b>	11/15/2012
<b>Decision Date:</b>	04/28/2014	<b>UR Denial Date:</b>	08/22/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/20/2013

### 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 Physical Medicine and Rehabilitation 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 51-year-old female who reported an injury on 11/15/2012. The mechanism of injury was noted to be the patient slipped on a comb and fell to the ground landing on her left arm and shoulder. The patient's medication history included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, ketoprofen, and cyclobenzaprine, as well as Cyclophene for greater than 1 year. The documentation of 07/14/2013 revealed the patient had pain in the neck, left shoulder, and left wrist, as well as low back. The patient had complaints of abdominal discomfort and indicated that her pain was alleviated with medications, rest, and activity restrictions. The request was made for medication refills, physical therapy and chiropractic treatment, a psychologist, TENS unit, and EMG/NCV. The patient's diagnoses included cervicalgia; cervical spine radiculopathy; left shoulder, left wrist, lumbosacral, and thoracic spine pain; lumbar spine radiculopathy; abdominal discomfort; anxiety, mood, and sleep disorders.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**RETROSPECTIVE REQUEST FOR KETOPROFEN 20% 120GM (7/27/2013): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, KETOPROFEN Page(s): 111-112.

**Decision rationale:** California MTUS indicates 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 indicated the patient had been taking the medication for greater than 1 year. There was lack of documentation indicating the patient had a trial and failure of antidepressants and anticonvulsants. Additionally, there was lack of documentation of the efficacy of the requested medication. Given the above, the retrospective request for ketoprofen 20% 120 grams (07/27/2013) is not medically necessary.

**RETROSPECTIVE REQUEST FOR CYCLOPHENE 5% 120GM (7/27/2013):** 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, TOPICAL MUSCLE RELAXANTS Page(s): 111, 113.

**Decision rationale:** California MTUS indicates 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. California MTUS Guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review indicated the patient had been taking the medication for greater than 1 year. There was lack of documentation indicating necessity for both an oral and topical form of cyclobenzaprine. There was lack of documentation indicating the efficacy of the requested medication. Given the above, the retrospective request for Cyclophene 5% 120 grams (07/27/2013) is not medically necessary.

**RETROSPECTIVE REQUEST FOR SYNAPRYN 10MG/LML 500ML (7/27/2013):**  
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 GLUCOSAMINE SULFATE, ONGOING MANAGEMENT, TRAMADOL Page(s): 50,78,82,93 & 94. Decision based on Non-MTUS Citation Synapryn online drug insert, FDA.gov

**Decision rationale:** California 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. California MTUS Guidelines recommend glucosamine sulfate for patients with moderate arthritis pain, especially knee osteoarthritis and that only 1 medication should be given at a time. Synapryn per the on-line 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 the VAS score, 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. The clinical documentation submitted for review indicated the patient had been taking the medication for greater than 1 year. There was lack of documentation indicating the patient had an objective decrease in the VAS score, an objective improvement in function, that the patient was being monitored for aberrant drug behavior, and that the patient was being monitored for side effects. Given the above, the retrospective request for Synapryn 10 mg/mL 500 mL (07/27/2013) is not medically necessary.

**RETROSPECTIVE REQUEST FOR TRABRADOL 1 MG/ML 250ML (7/27/2013):**

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 indicates 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 relaxant 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 American College of Occupational and Environmental Medicine (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. The clinical documentation submitted for review indicated the patient had been taking the medication for greater than 1 year. There was lack of documentation indicating necessity for both the topical and oral forms of cyclobenzaprine. There was lack of documentation of the efficacy of the requested medication. Given the above, the retrospective request for Tabradol 1 mg/mL 250 mL (07/27/2013) is not medically necessary.

**RETROSPECTIVE REQUEST FOR DICOPANOL 5 MG/ML 150ML (7/27/2013): 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](http://www.drugs.com/search.php?searchterm=dicopanol)

**Decision rationale:** [REDACTED].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 exceptional factors to warrant non-adherence to FDA regulations. The clinical documentation submitted for review indicated the patient had been taking the medication since 2012. There was lack of documentation indicating the efficacy of the requested medication. Given the above, the retrospective request for Dicopanol 5 mg/mL 150 mL (07/27/2013) is not medically necessary.

**RETROSPECTIVE REQUEST FOR FANATREX 25 MG/ML 420ML (7/27/2013): 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  
ANTIPILEPTIC DRUG Page(s): 16.

**Decision rationale:** 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. The clinical documentation submitted for review indicated the patient had been taking the medication for greater than 1 year. There was lack of documentation of the efficacy of the requested medication. Additionally, as this medication is not approved by the FDA, it is not supported by California MTUS Guidelines. Given the above, the retrospective request for Fanatrex 25 mg/mL 420 mL (07/27/2013) is not medically necessary.