

<b>Case Number:</b>	CM13-0036496		
<b>Date Assigned:</b>	12/13/2013	<b>Date of Injury:</b>	05/01/2010
<b>Decision Date:</b>	02/06/2014	<b>UR Denial Date:</b>	09/20/2013
<b>Priority:</b>	Expedited	<b>Application Received:</b>	11/01/2013

### 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 Pain Management, has a subspecialty in Disability Evaluation 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 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 38-year-old, right hand dominant, female who sustained an injury on May 1, 2010 while working as a Senior Fraud Analyst for [REDACTED]. The patient's usual and customary duties consisted of assisting customers by calling them regarding their accounts, dealing with collection calls regarding fraud, constant updating of information into a computer, etc. On the day of the injury, she was in the process of doing her regular and customary work duties, when she suddenly felt sharp pain in her right arm. The patient reported the injury and she received medical care in [REDACTED] where she was evaluated, underwent X-rays and was recommended physical therapy. She also received cortisone shots, underwent an MRI, and later on 12/14/2012 a surgical decompression of the ulnar nerve. Diagnoses include Ulnar neuritis and Right upper extremity pain.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Dicopanol 5m/mg oral suspension 150ml 1ml po at bedtime #1 (99070): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 06/07/13)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Insomnia, Treatment

**Decision rationale:** Dicopanor: CA MTUS Chronic pain and CA MTUS ACOEM are mute on the issue of the use of Dicopanor 5 mg/ml oral suspension 150 ml, 1 ml PO at bedtime #1. Dicopanor contains diphenhydramine and other proprietary ingredients. Many pharmacological agents currently on the market for the treatment of insomnia include benzodiazepines (i.e. temazepam) and non-benzodiazepines (i.e. zolpidem) hypnotics. Many of them carry the potential risk for addiction, cause withdrawal symptoms, or trigger rebound insomnia. Zolpidem, a commonly prescribed medication is categorized as a scheduled IV controlled substance by the DEA. It carries a warning label for abnormal thinking, behavioral changes, and/or amnesia like symptoms. Diphenhydramine is widely used in many non-prescription formulations. The records indicate the employee has difficulty sleeping due to pain. The California MTUS guidelines do not address the use of medications for the treatment of insomnia. The Official Disability Guidelines state that sedating antihistamines have been suggested for sleep aids, but tolerance seems to develop within a few days. The guidelines further state next day sedation has also been noted as well as impaired psychomotor and cognitive functions. A review of the records provided does not indicate the employee has been complaining of insomnia and no diagnosis of insomnia is listed. In addition, there is no indication as to why the employee cannot take an oral tablet or pill and requires an oral suspension. The requested Dicopanor oral suspension does not meet guideline recommendations. The request for Dicopanor (diphenhydramine) 5 mg/mL oral suspension 150 mL is not medically necessary or appropriate.

**Tabradol 1mg/1ml oral suspension 250ml 5ml/2-3x/day #1 (99070): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

**Decision rationale:** CA MTUS (Effective July 18, 2009) does not specifically address the request for Tabradol 1 mg/1 ml oral suspension. Tabradol contains cyclobenzaprine, methylsulfonylmethane and other proprietary ingredients. According to Chronic Pain Medical Treatment Guidelines MTUS (Effective July 18, 2009), ANTISPASMODICS which includes Flexeril also known as Cyclobenzaprine, are used to decrease muscle spasm in conditions such as low back pain although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known (Chou, 2004). They are recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine.

Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8 (ICSI, 2007) (Tofferi, 2004). The recommended dosage is 5-10mg thrice daily, for not longer than 2-3 weeks, with the greatest benefit in the first 4 days of therapy. The use of tobradol is not medically necessary nor appropriate.

**Compounded Cyclophene 5 percent in PLO Gel 120 grams #1 (99070): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 06/07/13)

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

**Decision rationale:** According to Chronic Pain Medical Treatment Guidelines 8 C.C.R. Â§Â§9792.20 - 9792.26 MTUS (Effective July 18, 2009) Pages 111-113 of 127, the use of topical analgesics is largely experimental with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed (Namaka, 2004). These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Cyclophene - Cyclophene gel 5% contains cyclobenzaprine. The provider states that in patients with musculoskeletal conditions, cyclobenzaprine has consistently been found to be effective in most clinical trials compared to other drugs in its class. The risk for dependence/abuse and withdrawal symptoms associated with narcotic drugs, the growing concern for potential abuse with the use of carisoprodol, and the side effect profile of other muscle relaxants, make cyclobenzaprine a better alternative. Cyclobenzaprine is effective in the treatment of musculoskeletal conditions such as low back pain, neck pain, fibrositis syndrome, muscle spasms, neuropathic pain, and chronic persistent pain with a limited temporal effectiveness of 1-2 weeks. This limited effectiveness pertains to the use of cyclobenzaprine in the oral formulation. The topical gel is used as a second line treatment and is not recommended for use according to the California MTUS Guidelines which do not recommend the use of cyclobenzaprine noting there is no evidence to support the use of any muscle relaxant as a topical product. There is little to no research to support the use of many of these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. According to MTUS (July 18, 2009) Chronic Pain Medical Treatment Guidelines page 113, there is no evidence for use of any muscle relaxant such as cyclobenzaprine as a topical product. Therefore, the request for compounded Cyclophene 5% in PLO gel is not medically necessary or appropriate.

**Compounded Ketoprofen 20 percent in PLO GEL 120 grams #1 (99070): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
Page(s): 64.

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

**Decision rationale:** CA-MTUS (Effective July 18, 2009) Topical Analgesics section pages 111-113 of 127 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo-contact dermatitis (Diaz, 2006) (Hindsen, 2006). Absorption of the drug depends on the base it is delivered in (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure (Krummel 2000). Cyclobenzaprine is mentioned for use only as an oral agent: page 64 of 127. It is generally not recommended also in accordance with page 113 of the California MTUS Chronic Pain Medical Treatment Guidelines which does not recommend the use of any muscle relaxants as a topical product . Therefore the request for topical Ketrop/Cyclo 20/20% is not medically necessary. The requested compounded Ketoprofen 20% in PLO gel at 120 gm is not medically necessary or appropriate.