

<b>Case Number:</b>	CM14-0053753		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	11/23/2011
<b>Decision Date:</b>	08/13/2014	<b>UR Denial Date:</b>	04/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/22/2014

### 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 Physical Medicine & Rehabilitation and is licensed to practice in California & Washington. 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 injured worker is a 76-year-old male who reported an injury on 11/23/2011. The mechanism of injury was a trip and fall. Prior treatments include chiropractic care and pain management. Additionally, the injured worker was treated previously with 6 different compounded creams and oral suspensions. The injured worker was noted to have a left knee total arthroplasty previously. Included in the medications were Ketoprofen and Cyclophene. The documentation of 03/07/2014 revealed a request for compounded Ketoprofen and compounded Cyclophene. The other medications that were requested were Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. The documentation of 03/10/2014 revealed Ketoprofen was recommended as NSAIDs have been widely accepted by the medical community and used in Europe for over 10 years. The documentation further indicated that Cyclophene includes cyclobenzaprine hydrochloride and other proprietary ingredients. It was further noted that cyclobenzaprine has consistently been found to be effective in most clinical trials compared to other drugs in its class.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compound Medication: Ketoprofen 20 in Gel 120 grams, Cyclophene 5 in PLO Gel, 120 grams:** 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, Topical Analgesics, Topical Muscle Relaxants, Cyclobenzaprine  
Page(s): 111, 112, 113, page 41.

**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 failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The documentation indicated the injured worker had utilized at least 6 topical creams. However, the duration of use could not be established through supplied documentation. The request as submitted failed to indicate the frequency for the Ketoprofen topical. This portion of the request would not be supported. 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 failed to provide the injured worker had a trial and failure of anticonvulsants and antidepressants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The duration of use could not be established. However, it was indicated the injured worker was utilizing topical analgesics for an extended duration of time. The request as submitted failed to indicate the frequency for the requested medication. As such, cyclophene would not be supported. Given the above, the request for compounded medication Ketoprofen 20 in gel 120 grams, cyclophene 5 in PLO gel 120 grams is not medically necessary.