

<b>Case Number:</b>	CM13-0060079		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	02/08/2012
<b>Decision Date:</b>	05/08/2014	<b>UR Denial Date:</b>	11/20/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/03/2013

### 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 injured worker is a 54-year-old female who reported injury on 02/08/2012. The mechanism of injury was a fall. The documentation of 10/10/2013 revealed the injured worker was to have an arthroscopy of the left shoulder with rotator cuff repair. The diagnosis was pain joint. The request was made for Dyotin SR, Theraflex cream, and Biotherm pain relieving lotion.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**THERAFLEX 180G 20%/10%/4% TO BE APPLIED 304 TIMES DAILY:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen; Topical Analgesics ; Cyclobenzaprine Page(s): 72, 111, 41.

**Decision rationale:** California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical (NSAIDs) non-steroidal anti-inflammatory drugs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is

classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. 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 addition of cyclobenzaprine to other agents is not recommended. The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and that trials of antidepressants and anticonvulsants had failed. There was lack of documentation of exceptional factors to warrant nonadherence to guideline and FDA regulations. There was an inability to establish the duration for the requested medication with the supplied documentation. Given the above, the request for Theraflex 180 g 20%/10%/4% to be applied 304 times daily is not medically necessary.