

<b>Case Number:</b>	CM13-0057568		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	12/01/2012
<b>Decision Date:</b>	05/21/2014	<b>UR Denial Date:</b>	11/12/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2013

### 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 37 year-old male who reported an injury on 12/01/2012 and the mechanism of injury was from performing a work related physical activity. The current diagnosis is enthesopathy of elbow region. The patient's medication included topical creams Fluriflex 180mg in morning and TGHOT 180mg in the evening. The injured worker indicated that he continued to have chronic pain in the bilateral elbows/forearm and bilateral hands/wrist with some improvements noted. The clinical note from 09/12/2013 on examination of the bilateral elbows and bilateral wrist revealed there was tenderness to palpation and palpable spasm with full range of motion. The topical medications we prescribed in order to minimize possible neurovascular complication, to avoid complications associated with the use of narcotic medication, and upper gastrointestinal bleeding from the use of NSAID's medications. The current request is for TGHOT 180GM (PM) and FLURIFLEX 180GM (AM) dated 10/25/2013.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TGHOT 180GM (PM):** 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 TRAMADOL, GABAPENTIN, TOPICAL CAPSAICIN, TOPICAL ANALGESICS, TOPICAL SALICYLATES Page(s): 82, 11.

**Decision rationale:** The California MTUS indicated that topical analgesics are largely experimental in use 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended. 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, which is not recommended as a first line therapy. Gabapentin is not recommended and there is no peer-reviewed literature to support use. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not medically necessary. As such, the request for TGHOT 180GM (PM) is non-certified.

**FLURIFLEX 180GM (AM):** 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 FLURBIPROFEN, TOPICAL ANALGESICS, CYCLOBENZAPRINE Page(s): 72, 111, 41.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use 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. Topical NSAIDs 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. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. The 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. Therefore, the request for FLURIFLEX 180GM (AM) is not medically necessary and is non-certified.