

<b>Case Number:</b>	CM14-0019282		
<b>Date Assigned:</b>	04/21/2014	<b>Date of Injury:</b>	10/19/2012
<b>Decision Date:</b>	07/02/2014	<b>UR Denial Date:</b>	01/31/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/14/2014

### 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 Family Medicine and is licensed to practice in Texas. 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 53-year-old female who reported an injury on 10/19/2012 secondary to an unknown mechanism of injury. Her diagnoses include right shoulder rotator cuff tear, lateral epicondylitis, wrist sprain, and hand pain. The injured worker was evaluated on 01/16/2014 and reported weakness and pain in her right arm. It was reported that she was using a TENS unit and continued with limited range of motion. On physical examination, she was noted to have tenderness to palpation of the right shoulder and loss of strength. Her medications were noted to include cyclobenzaprine, Dyotin, Flurbitac, TheraFlex cream, Keratek gel, Vicosetron, and Midazolam. According to the medical records submitted for review, the injured worker used creams on an as needed basis since at least 12/10/2013. The injured worker reported that the lotions prescribed were "helping to alleviate pain." The injured worker was recommended to continue medications. The request for authorization was submitted on 01/24/2014 for the above named medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**THERAFLEX CREAM/KERATEK GEL:** 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 Page(s): 111-113.

**Decision rationale:** The request for TheraFlex cream/Keratek gel is non-certified. TheraFlex cream is a compounded topical medication that contains 20% Flurbiprofen, 10% Cyclobenzaprine, and 4% menthol. The California MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These guidelines state that there is no evidence for use of any muscle relaxants such as Cyclobenzaprine as a topical product. Additionally, the guidelines state that any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. As TheraFlex cream contains at least 1 drug that is not recommended, TheraFlex cream is not recommended. Furthermore, the request as written does not include a quantity of medication requested. Therefore, it cannot be determined that the requested medication allows for timely reassessment of medication efficacy. Moreover, medical records indicate that the injured worker has used topical creams since at least 12/10/2013. She reported that they were “helping to alleviate pain.” There is a lack of recently documented evidence to indicate quantifiable pain relief and objective functional improvement with the injured worker’s use of topical medications. In the absence of documentation of quantifiable pain relief and objective functional improvement, and based on evidence based guideline recommendations regarding topical analgesics, the necessity of TheraFlex cream/Keratek gel has not been established. As such, the request for TheraFlex cream/Keratek gel is not medically necessary.