

<b>Case Number:</b>	CM14-0128299		
<b>Date Assigned:</b>	08/15/2014	<b>Date of Injury:</b>	09/24/2013
<b>Decision Date:</b>	10/03/2014	<b>UR Denial Date:</b>	07/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/12/2014

### 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 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 patient is a 44-year-old female who has submitted a claim for bilateral knees, bilateral ankles, and bilateral feet pain associated with an industrial injury date of 09/24/2013. Medical records from 02/11/2014 to 07/04/2014 were reviewed and showed that patient complained of bilateral knees, bilateral ankles, and bilateral feet pain graded 5-8/10. Physical examination of the bilateral knees revealed tenderness over medial joint line, MMT of 4/5 in quadriceps, and positive varus, valgus, and McMurray's tests. Physical examination of the bilateral ankles/feet revealed tenderness over medial and lateral sub-malleoli region and Achilles tendon. Treatment to date has included Flurbiprofen/ Cyclobenzaprine/Menthol Cream (20%/10%/4%) 180 g (prescribed since 05/13/2014), Kera-Tek Analgesic gel (DOS: 07/22/2014), and oral pain medications such as Motrin. Of note, there was no documentation of intolerance to oral pain medications. There was no documentation of functional outcome from topical medications. Utilization review dated 07/22/2014 denied the request for Flurbiprofen/ Cyclobenzaprine/Menthol Cream (20%/10%/4%) and Kera-Tek Analgesic gel because the compounded medications were not FDA approved and there was lack of trial of more generally recognized medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**The compound medication Flurbiprofen/Cyclobenzaprine/Menthol Cream (20%/10%/4%), 180gm,:** 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Salicylates, Topical

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Fluriflex cream contains 2 active ingredients; Flurbiprofen and Cyclobenzaprine. Regarding Flurbiprofen, CA MTUS supports a limited list of NSAID topical which does not include Flurbiprofen. Regarding Cyclobenzaprine, guidelines state that there is no evidence to support the use of cyclobenzaprine as a topical compound. , CA MTUS does not cite specific provisions, but the ODG Pain Chapter issued an FDA warning indicating that topical OTC pain relievers that contain menthol, or methyl salicylate, may in rare instances cause serious burns. In this case, the patient was prescribed Flurbiprofen/ Cyclobenzaprine/Menthol Cream (20%/10%/4%) 180 g since 05/13/2014. However, the compounded cream contained both flurbiprofen and cyclobenzaprine which are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request likewise failed to specify the quantity of compounded cream to be dispensed. Therefore, the request for the compound medication Flurbiprofen/Cyclobenzaprine/Menthol Cream (20%/10%/4%), 180gm is not medically necessary.

**Kera-Tek analgesic 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 Salicylate Topicals, Topical Analgesics Page(s): 105, 111. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Salicylates, Topical

**Decision rationale:** According to page 111 of CA MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Keratek gel contains 28% methyl salicylate and 16% menthol. Page 105 states that the guidelines support the topical use of methyl salicylates; the requested Keratek has the same formulation as over-the-counter products such as BenGay. It has not been established that there is any necessity for this specific brand name. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter issued an FDA warning indicating that topical OTC pain relievers that contain menthol, or methyl salicylate, may in rare instances cause serious burns. In this case, the patient was prescribed Kera-Tek Analgesic gel (DOS: 07/22/2014). There was no documentation of intolerance to oral pain medications. There was no discussion as to why over-the-counter products would not suffice when they have the same formula as Kera-tek gel. The request

likewise failed to specify the quantity of compounded cream to be dispensed. Therefore, the request for Kera-Tek Analgesic gel is not medically necessary.