

<b>Case Number:</b>	CM14-0071156		
<b>Date Assigned:</b>	06/04/2014	<b>Date of Injury:</b>	06/25/2008
<b>Decision Date:</b>	08/11/2014	<b>UR Denial Date:</b>	04/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/16/2014

### 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 Occupational Medicine 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 57-year-old male who has submitted a claim for bilateral shoulder pain and bilateral knee pain, associated with an industrial injury date of June 25, 2008. Medical records from 2013 through 2014 were reviewed. Progress reports showed neck and back pain radiating to bilateral upper and lower extremities. Bilateral knees were also painful. Physical examination revealed tenderness in bilateral shoulders with decreased strength in the internal and external rotation of bilateral shoulders. The patient was diagnosed with gastroesophageal Reflux Disease, secondary to NSAIDs. Treatment to date has included bilateral shoulder surgery, right knee arthroscopic surgery and medications. Utilization review from 04/19/2014 denied the request for the purchase of Keratek gel for bilateral knees and bilateral shoulders because medical necessity was not established by the documentation or supported guidelines for the prescribed topical compound medication.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **KERATEK GEL FOR THE BILATERAL KNEES AND BILATERAL SHOULDERS:**

Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**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 Section, Topical Salicylate.

**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 rationale of using a topical gel is to reduce impact of the Gastroesophageal Reflux Disease secondary to NSAID usage. However, guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. Keratek gel contains drug components that are not recommended for topical use. Furthermore, the present request does not specify the amount of medication to dispense. Therefore, the request for Keratek gel for bilateral knees and bilateral shoulders is not medically necessary.