

<b>Case Number:</b>	CM15-0148075		
<b>Date Assigned:</b>	08/11/2015	<b>Date of Injury:</b>	12/20/2008
<b>Decision Date:</b>	09/30/2015	<b>UR Denial Date:</b>	07/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/30/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 48 year old male, who sustained an industrial injury on December 20, 2008. He reported left knee pain and discomfort. The injured worker was diagnosed as having osteoarthritis of knee, unspecified and pain in joint, shoulder region. Treatment to date has included diagnostic studies, radiographic imaging, physical therapy, medications and work restrictions. Currently, the injured worker continues to report persistent pain, swelling and stiffness with limited range of motion of the left knee. He also reported feelings of popping and warmth with some discoloration noted. The injured worker reported an industrial injury in 2008, resulting in the above noted pain. He was treated conservatively without complete resolution of the pain. Evaluation on January 22, 2015, revealed continued pain with associate symptoms as noted. He was to remain off work until March 15, 2015. Topical and oral medications, physical therapy, home exercises and heat and ice applications were continued. Evaluation on June 4, 2015, revealed continued pain as noted. He reported clicking and swelling in the left knee. Physical therapy was completed. Three view x-rays revealed no increase in osteoarthritis. Flurbiprofen 20%, Cyclobenzaprine 10%, Menthol 4% cream and KeraTek Gel 4 oz. bottle, Qty 113 were requested.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**KeraTek Gel 4 oz bottle, Qty 113: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Kera-Tek contains methyl salicylate and menthol. Methyl salicylate may have an indication for chronic pain in this context. Per MTUS page 105, recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS page 60 states only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually. As menthol is not recommended, the request is not medically necessary.

**Flurbiprofen 20%, Cyclobenzaprine 10%, Menthol 4% cream: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60 and 111-113.

**Decision rationale:** Per MTUS with regard to Flurbiprofen (p112), these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Per MTUS CPMTG page 113, "There is no evidence for use of any other muscle relaxant as a topical product. [Besides baclofen, which is also not recommended]" Cyclobenzaprine is not indicated. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications 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. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006)

Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of tramadol, menthol or camphor. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since several components are not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS page 60 states only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually. Because topical cyclobenzaprine is not indicated, the compound is not recommended. This request is not medically necessary.