

<b>Case Number:</b>	CM15-0212093		
<b>Date Assigned:</b>	10/30/2015	<b>Date of Injury:</b>	09/21/2014
<b>Decision Date:</b>	12/16/2015	<b>UR Denial Date:</b>	10/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/28/2015

### 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

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 28 year old female, who sustained an industrial injury on September 21, 2014. The injured worker was diagnosed as having lumbar sacral disc herniation at lumbar five to sacral one. Treatment and diagnostic studies to date has included x-rays of the thoracic and lumbar spine, medication regimen, physical therapy with the quantity unknown, and extracorporeal shockwave treatments. In a progress note dated October 05, 2015 the treating physician reports complaints of "severe" pain to the thoraco-lumbar spine that radiates to the left lower extremities. Examination performed on October 05, 2015 was revealing for burning sensation to the low back that radiates to the left lower extremity. The progress note from October 05, 2015 did not include the injured worker's current medication regimen. The injured worker's pain level on October 05, 2015 was rated a 7 on a scale of 1 to 10. The progress note from April 21, 2015 noted prescriptions for Amitriptyline, Gabapentin, Bupivacaine cream and Flurbiprofen, Baclofen, Camphor, Dexamethasone, Menthol, Capsaicin cream, but the medical records did not indicate if the injured worker's pain level decreased or if the injured worker experienced any functional improvement with activities of daily living with these above listed medications. On October 05, 2015 the treating physician requested Kera Tek Gel 4oz for pain and inflammation and Flurbiprofen, Cyclobenzaprine, and Menthol cream (20%, 10%,4%) 180gm for pain. On October 27, 2015 the Utilization Review denied the requests for Kera Tek Gel 4oz and Flurbiprofen, Cyclobenzaprine, and Menthol cream (20%, 10%,4%) 180gm.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Kera Tek gel 4oz:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The current request is for Kera Tek Gel 4oz. Treatment and diagnostic studies to date has included x-rays of the thoracic and lumbar spine, medication regimen, physical therapy and extracorporeal shockwave treatments. The patient may return to modified duty. Kera-Tek analgesic gel contains Menthol 16g in 100g and Methyl Salicylate 28g in 100g. MTUS, Topical Analgesics Section, pages 11-113 states they are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and recommends for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Methyl salicylate and menthol are recommended under MTUS Salicylate topical section, page 105 in which Ben-Gay (which contains menthol and methyl salicylate) is given as an example and is stated as significantly better than placebo in chronic pain. Topical NSAIDs are indicated for peripheral joint arthritis/tendinitis problems. "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. Neuropathic pain: Not recommended as there is no evidence to support use." Per report 10/05/15, the patient presents with chronic pain to the thoraco-lumbar spine that radiates to the left lower extremities. Examination revealed a burning sensation to the low back that radiates to the left lower extremity. The patient has a diagnosis of intervertebral disc disorder with radiculopathy of the lumbar region. The patient was given a prescription for Keratek topical gel for pain and inflammation. This patient presents with chronic back pain, and MTUS supports the use of methyl salicylate for peripheral joint arthritis/tendinitis condition, which the patient does not present with. Guidelines do not support topical Keratek for treatment of osteoarthritis of the spine, hip or shoulder. This request is not in accordance with guidelines. Therefore, the request is not medically necessary.

**Flurbiprofen/Cyclobenzaprine/Menthol cream (20%/10%/4%), 180gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The current request is for Flurbiprofen/Cyclobenzaprine/Menthol Cream (20%/10%/4%), 180GM. Treatment and diagnostic studies to date has included x-rays of the thoracic and lumbar spine, medication regimen, physical therapy and extracorporeal shockwave treatments. The patient may return to modified duty. MTUS Guidelines, Topical Analgesics

section, page 111-113 has the following under Other Muscle Relaxants: "There is no evidence for use of any other muscle relaxant as a topical product." Under Non-steroidal antiinflammatory agents: "The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. 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 class in general is only recommended for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist)." MTUS Guidelines, Topical Analgesics section, page 111 also states that "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Per report 10/05/15, the patient presents with chronic pain to the thoraco-lumbar spine that radiates to the left lower extremities. Examination revealed a burning sensation to the low back that radiates to the left lower extremity. The patient has a diagnosis of intervertebral disc disorder with radiculopathy of the lumbar region. In regard to the topical compounded cream containing Flurbiprofen, Cyclobenzaprine, and Menthol, the requested topical cream is not supported by MTUS guidelines. Flurbiprofen is only recommended for peripheral joint arthritis and tendinitis, and this patient presents with back pain with a radicular component. In addition, MTUS guidelines do not support muscle relaxants such as Cyclobenzaprine in topical formulations. Therefore, this request is not medically necessary.