

<b>Case Number:</b>	CM15-0212891		
<b>Date Assigned:</b>	11/02/2015	<b>Date of Injury:</b>	07/22/2013
<b>Decision Date:</b>	12/21/2015	<b>UR Denial Date:</b>	10/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/29/2015

### 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: Texas, California  
 Certification(s)/Specialty: Family Practice

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 54-year-old male patient, who sustained an industrial injury on 7-22-2013. Diagnoses include progressive degenerative disc disease at L5-S1 with collapse and foraminal stenosis, back pain with radiculopathy, status post right L5-S1 microdiscectomy. Per the doctor's note dated 7-23-15, he had complaints of ongoing low back pain. The physical examination documented lumbar tenderness with numbness, tingling, and weakness in the legs. The plan of care included a functional capacity evaluation (FCE) and topical compound creams. Per the doctor's note dated 9-24-15, he had complaints of increasing low back pain with radicular symptoms. There was no change in the physical examination. The records indicated he was waiting for lumbar surgical intervention approval. The medications list includes norco, omeprazole, amlodipine, metoprolol, alprazolam, atorvastatin and aspirin. He had lumbar MRI dated 8/4/15. He has undergone right L5-S1 microdiscectomy. Treatments to date include activity modification, anti-inflammatory, physical therapy, and lumbar epidural injections. The appeal requested authorization for Kera Tek Gel (Methyl Salicylate-Menthol) transdermally, 4 ounce bottle daily, apply 1-2 grams 2-3 times per day, no refills, prescribed 7-23-15; and Flurbiprofen-Cyclobenzaprine-Menthol Cream 20%-10%-4% transdermally, 180grams, apply 1-2 grams 2-3 times per day, prescribed 7-23-15, date of service 9-11-15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Kera Tek Gel (Methyl Salicylate/Menthol) transdermally, 4 ounce bottle, apply 1-2 grams 2-3 times per day as directed, no refills (prescribed 7/23/15, DOS: 9/11/15): 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:** Retrospective Kera Tek Gel (Methyl Salicylate/Menthol) transdermally, 4 ounce bottle, apply 1-2 gram....Keratek gel contains menthol and methyl salicylate.MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "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. There is little to no research to support the use of many of these agents...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Failure of antidepressants or anticonvulsant was not specified in the records provided. Any intolerance or lack of response to oral medications is not specified. Any compounded product that contains at least one drug (or drug class) that is not recommended. There is no high-grade clinical evidence to support the effectiveness of topical menthol in lotion form. The medical necessity of Retrospective Kera Tek Gel (Methyl Salicylate/Menthol) transdermally, 4 ounce bottle, apply 1-2 gram was not fully established for this patient at this juncture.

**Retrospective Flurbiprofen/Cyclobenzaprine/Menthol Cream 20%/10%/4% transdermally, 180gm, apply 1-2 grams 2-3 times per day or as directed (prescribed 7/23/15, DOS: 9/11/15): 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:** Retrospective Flurbiprofen/Cyclobenzaprine/Menthol Cream 20%/10%/4% transdermally, 180gm, apply 1-2 gram....Flurbiprofen is an NSAID and cyclobenzaprine is a muscle relaxant.The cited Guidelines regarding topical analgesics state, "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. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants..). (Argoff, 2006) There is little to no research to support the use of many of these agents." Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. "Topical NSAIDs- 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..."Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The cited guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Failure of antidepressants and anticonvulsants for this injury was not specified in the records provided. Intolerance to oral medication was not specified in the records provided. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen and cyclobenzaprine are not recommended by the cited guidelines for topical use as cited below because of the absence of high grade scientific evidence to support their effectiveness. The medical necessity of Retrospective Flurbiprofen/Cyclobenzaprine/Menthol Cream 20%/10%/4% transdermally, 180gm, apply 1-2 gram was not fully established for this patient.