

<b>Case Number:</b>	CM14-0089019		
<b>Date Assigned:</b>	07/23/2014	<b>Date of Injury:</b>	11/25/2013
<b>Decision Date:</b>	08/28/2014	<b>UR Denial Date:</b>	05/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/13/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Texas. 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 injured worker is a 30 year old male who sustained an injury on 11/25/13. The injured worker was unloading tires when he developed complaints of low back pain with radiating features in the lower extremities. Prior treatment has included physical therapy which the injured worker attended for approximately one month. MRI studies did report evidence of a torn meniscus in the right knee and the injured worker did undergo a prior right knee arthroscopy in December of 2013. The injured worker has also been followed by pain management for continuing low back pain radiating to the lower extremities. The injured worker did report taking Naproxen. The injured worker's physical exam from 04/23/14 noted restricted lumbar range of motion with positive straight leg raise bilaterally to the right at 45 degrees into the left at 30 degrees. There was a positive Faber's sign to the left. Sensation was noted to be intact. There was noted weakness in the right lower extremity and a global distribution. No reflex changes were identified. The injured worker was pending an epidural steroid injection at this evaluation. Follow-up on 06/02/14 noted that the injured worker was taking Tylenol 3, 2-3 tablets per day. This medication did improve pain from 8/10 to 4/10 on the visual analog scale (VAS). Physical exam continued to note loss of lumbar range of motion with decreased sensation in a L4 through S1 distribution to the right lower extremity. The injured worker was again recommended for epidural steroid injections. It is noted that the urine drug screen report from 06/02/14 was negative for evidence of Codeine use. Follow up on 07/01/14 noted no specific change in the injured worker's physical exam findings. The injured worker was continued on Tylenol 3 despite the negative urine drug screen report. There was a request for a 30 day Transcutaneous Electrical Nerve Stimulation (TENS) unit trial. The requested Kera-tek analgesic gel and a compounded topical medication that includes Flurbiprofen/ Cyclobenzaprine and Menthol were both denied by utilization review on 05/16/14.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Kera-tek Analgesic Gel:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain/Formulary.

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

**Decision rationale:** In regards to the use of Kera-Tek gel, this reviewer would not have recommended this medication as medically necessary based on the clinical documentation provided for review and current evidence based guideline recommendations. Kera-Tek gel contains Menthoderm, which is available as a commercial over-the-counter topical analgesic. The clinical documentation submitted for review as well as current evidence base guidelines do not support the request. There is no documentation of functional improvement on this medication. According to CA MTUS guidelines, this medication is largely experimental in use with few randomized controlled trials to determine efficacy or safety. Therefore medical necessity has not been established.

**Flurbiprofen/Cyclobenzaprine/Menthol Cream (20%/10%4%):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

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

**Decision rationale:** In regards to the use of Compounded topical medication to include Flurbiprofen/ Cyclobenzaprine, and Menthol cream, this reviewer would not have recommended this medication as medically necessary based on the clinical documentation provided for review and current evidence based guideline recommendations. The CA MTUS and US FDA note that the efficacy of compounded medications has not been established through rigorous clinical trials. The FDA requires that all components of compounded topical medication be approved for transdermal use. This compound contains Flurbiprofen and Cyclobenzaprine which are not approved for transdermal use. The clinical documentation provided did not discuss the claimant's prior medication use and did not indicate that there were any substantial side effects with the oral version of the requested medication components. Therefore, this compound cannot be supported as medically necessary.