

Case Number:	CM14-0155352		
Date Assigned:	09/25/2014	Date of Injury:	10/26/1998
Decision Date:	10/27/2014	UR Denial Date:	08/26/2014
Priority:	Standard	Application Received:	09/23/2014

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 Physical Medicine and Rehabilitation 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 41-year-old male who has submitted a claim for sprain lumbar region associated with an industrial injury date of 10/26/1998. Medical records from 04/09/2014 to 09/12/2014 were reviewed and showed that patient complained of low back pain graded 3/10 with radiation down the right leg. Physical examination revealed decreased lumbar range of motion (ROM), tenderness over right lumbar paraspinal muscles, hypesthesia of right S1 distribution, and normal strength and reflexes of lower extremities. MRI of the lumbar spine dated 08/26/2014 revealed mild degenerative changes at L4-5 and L5-S1 with no signs of nerve compromise. X-ray of the lumbar spine dated 04/09/2014 revealed L5-S1 disc space narrowing. Treatment to date has included physical therapy, chiropractic treatment, oral pain medications such as Ultram and Motrin, Kera-tek gel (quantity not specified; prescribed since 04/09/2014), and Flurbiprofen/Cyclobenzaprine/Menthol cream (20%/10%/4%) 180 gm (quantity not specified; prescribed since 07/11/2014). Of note, there was no documentation of functional outcome from topical medications or physical therapy. There was no documentation of intolerance to oral pain medications, either. Utilization review dated 08/28/2014 denied the request for Flurbiprofen/Cyclobenzaprine/Menthol cream (20%/10%/4%) 180 gm because the guidelines do not support the topical use of Flurbiprofen, Cyclobenzaprine, or Menthol. Utilization review dated 08/28/2014 denied the request for Kera-tek gel (menthol, methyl salicylate) because menthol was not recommended by the guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Cyclobenzaprine/Menthol cream (20%/10%/4%) 180 gm: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Salicylates

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Regarding Flurbiprofen, the MTUS supports a limited list of NSAIDs (non-steroidal anti-inflammatory drugs) in topical form; that list does not include Flurbiprofen. Regarding Cyclobenzaprine, guidelines state that there is no evidence to support the use of Cyclobenzaprine as a topical compound. The ODG Pain Chapter issued an FDA safety warning which identifies rare cases of serious burns that have been reported to occur on the skin where over-the-counter (OTC) topical muscle and joint pain relievers were applied. These products contain the active ingredients Menthol, Methyl Salicylate, or Capsaicin. In this case, the patient was prescribed Flurbiprofen/ Cyclobenzaprine/ Menthol cream (20%/10%/4%) since 07/11/2014. However, there was no documentation of functional outcome from previous Flurbiprofen/Cyclobenzaprine/Menthol cream use. Moreover, the compounded cream contains Flurbiprofen and Cyclobenzaprine that are both not recommended for topical use by the guidelines. The guidelines clearly state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for Flurbiprofen/Cyclobenzaprine/Menthol cream (20%/10%/4%) 180 gm is not medically necessary.

Kera-Tek analgesic gel: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals and Topical Analgesics Page(s): 105 and 111. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Salicylates, Topical

Decision rationale: According to page 111 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Kera-tek gel contains 28% methyl salicylate and 16% menthol. Page 105 states that the guidelines support the topical use of methyl salicylates; the requested Kera-tek has the same formulation as over-the-counter (OTC) products such as BenGay. It has not been established that there is any necessity for this specific brand name. Regarding the Menthol component, the 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 patient

was prescribed Kera-tek gel since 04/09/2014. However, there was no documentation of functional outcome from previous Kera-tek gel use. Moreover, the guidelines state that Kera-tek has the same formulation as over-the-counter product such as BenGay. There was no discussion as to why over-the-counter products will not suffice. Furthermore, there was no discussion of intolerance to oral pain medications to support Kera-tek gel use. The request likewise failed to specify the quantity of Kera-tek gel to be dispensed. Therefore, the request for Kera-tek analgesic gel is not medically necessary.