

Case Number:	CM14-0177936		
Date Assigned:	10/31/2014	Date of Injury:	11/27/2012
Decision Date:	02/04/2015	UR Denial Date:	10/14/2014
Priority:	Standard	Application Received:	10/27/2014

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 Internal Medicine and is licensed to practice in Pennsylvania. 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:

This is a 63 year-old female who has reported widespread pain after falling on 11/27/2012. Diagnoses have included lumbar and cervical sprain/strain, right shoulder impingement, and knee arthralgia. Treatment has included right shoulder injection, a shoulder decompression with rotator cuff repair on 12/13/2013, physical therapy, modified work duties, and medications. The treating surgeon has submitted periodic reports since the surgery in 2013. Reports during 2014 reflect ongoing widespread pain, prescribing of Motrin, topical compounded medications, Kera-Tek gel, Ultram, codeine, Prilosec, Lidoderm; temporarily totally disabled work status, and specific increases in function. Kera-Tek was prescribed on 6/19/14, with no subsequent reports of results. A urine drug screen on 4/28/14 was positive for codeine, hydrocodone, and morphine. Only codeine was listed as a current prescribed medication. There are no treating physician reports which discuss this urine drug screen result. On 09/25/2014 there was ongoing neck, back, and all-extremity pain rated as 5-9/10. Medications are reported to decrease pain from 10 to 8-9. She was not working. The injured worker had been using Lidoderm patch, sleep medication, Vicodin two tablets a day as needed, and ibuprofen. The specific ingredients of Kera-Tek and their indications were not discussed. There was widespread tenderness with limited range of motion. The treatment plan included Prilosec, Vicodin, and Kera-Tek gel. Work status was temporarily totally disabled. On 10/14/14 Utilization Review non-certified Kera-Tek gel and certified #60 of the #90 of Vicodin that were requested. The MTUS and the Official Disability Guidelines were cited. Kera-Tek was partially certified for a similar OTC product with the same ingredients; the Utilization Review stated that it has not been established that there is any necessity for this specific brand name drug. The reason for the modification of the Vicodin by Utilization Review was given as Vicodin should be weaned.

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.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Medications for chronic; Salicylate topical Page(s): 111-113; 60; 105. Decision based on Non-MTUS Citation FDA Drug Safety Communication: Rare cases of serious burns with the use of over-the-counter topical muscle and joint pain relievers, 9/13/2012

Decision rationale: Kera Tek is a compounded topical analgesic that contains 28% Salicylate and 16% Menthol. The treating physician did not discuss the indications or reasons for using this high concentration of active ingredients. The treating physician did not discuss the results of prior use of Kera Tek, as would be necessary per the MTUS citation above (page 60, medications for chronic pain). The MTUS recommends that all medications for chronic pain be assessed for symptomatic and functional gains. The FDA issued a warning for topical salicylates and menthol with higher concentrations, as these can cause burns. There is no evidence that the treating physician trialed lower concentrations less likely to cause burns. Kera Tek appears to be a compounded product that is not FDA approved, and would be experimental as a result. The MTUS, cited above, recommends topical salicylates and mentions Ben-Gay. Kera Tek is not medically necessary due to lack of any clear benefit from prior use, the non-FDA approved formulation, the FDA warnings, and the lack of any trial of a lower concentration.

Vicodin (Hydrocodone and Acetaminophen 5/325mg) #90, Sig: 1-2 tablets by mouth every 6-8 hours as needed for pain with no refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone/Acetaminophen.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Management; Opioids, steps to avoid misuse/addiction; indications, Chronic back pain; Mec.

Decision rationale: There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. There should be specific functional goals including return to work, with random drug testing and opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. The urine drug screen in April 2014 had inconsistent results were not addressed by the physician. Pain levels remain high. The prescribing physician does not specifically address function with respect to prescribing opioids. The prescribing physician describes this patient as "temporarily totally disabled", which generally represents a profound failure of treatment, as this implies confinement to bed for most or all of the day. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial

of non-opioid analgesics." Based on the failure of prescribing per the MTUS, the urine drug screen inconsistent with prescribed medications and the lack of specific functional benefit, Vicodin #90 with no refills is not medically necessary.