

Case Number:	CM14-0143131		
Date Assigned:	09/10/2014	Date of Injury:	06/22/2005
Decision Date:	12/17/2014	UR Denial Date:	08/19/2014
Priority:	Standard	Application Received:	09/04/2014

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 Massachusetts. 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:

According to the documents available for review, the patient is an injured female worker. The date of injury is 6/22/05. The patient sustained an injury to the lumbar spine. The specific mechanism of injury was not fully elaborated on in the notes available for review. The patient currently complains of pain in the low back and legs, worse with ambulation and activity. The patient is maintained on the multimodal pain medication regimen including Ker Tek Gel, Flurb/Cyclo/Mentho Cream, Motrin and Ultram. A request for Ker Tek Gel, Flurb/Cyclo/Mentho Cream, Motrin and Ultram was denied.

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 Treatment Guidelines Topical Analgesics.

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

Decision rationale: According to the MTUS, there is little to no research to support the use of topical compounded creams. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal

required. Topical analgesics are largely experimental and there are a few randomized controlled trials to determine efficacy or safety. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Flurb 20%/Cyclo 10%/Menth 4% Cream 180gm: 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: According to the MTUS, there is little to no research to support the use of topical compounded creams. It also contains menthol, a non-recommended topical agent. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Topical analgesics are largely experimental and there are a few randomized controlled trials to determine efficacy or safety. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Motrin 800mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67, 70-73.

Decision rationale: According to the MTUS Anti-inflammatories are the traditional first lines of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) Recommended with cautions below: Disease-State Warnings for all NSAIDs: All NSAIDS have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDS should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been

established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. According to the documents available for review, it appears that the patient is taking this medication for long-term therapy of a chronic condition. Given the increased risks associated with long-term use of this medication and no documented evidence that the lowest possible dose is being used for the shortest period of time, the requirements for treatment have not been met and medical necessity has not been established.

Ultram 50mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management Page(s): 74-97.

Decision rationale: According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.(b) The lowest possible dose should be prescribed to improve pain and function.(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. There is no current documentation of baseline pain, pain score

with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and as required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.