

Case Number:	CM13-0017640		
Date Assigned:	06/06/2014	Date of Injury:	02/24/2000
Decision Date:	12/23/2014	UR Denial Date:	08/26/2013
Priority:	Standard	Application Received:	08/28/2013

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 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 an injured worker who is status post bilateral total knee replacement surgeries. Date of injury was 02-24-2000. The progress report dated 5/20/13 documented subjective complaints of left knee pain. Objective findings included normal gait. Left knee had normal range of motion. There was a history of motor vehicle accident. Treatment plan included Terocin. The progress report dated July 22, 2013 documented subjective complaints of knee pain. His left knee still has some inflammation. Pain level is tolerable 1-2/10. Diagnosis was bilateral total knee replacements. Objective findings were documented. Blood pressure was 120/82. Pulse was 90. Pain level was 2/10. The treatment plan included Vicodin and Terocin. Utilization review determination date was 8/28/13.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin 240 Dos 7/22/2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin, topical, NSAIDs Page(s): 111-113, 28-29, 69-70. Decision based on Non-MTUS Citation Terocin, <http://www.drugs.com/pro/terocin.html>.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. Capsaicin is only an option in patients who have not responded or are intolerant to other treatments. Besides Lidoderm, no other commercially approved topical formulation of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). Use of NSAIDs may compromise renal function. FDA medication guide recommends lab monitoring of a CBC and chemistry profile (including liver and renal function tests). Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Terocin is a topical analgesic, containing methyl salicylate, Capsaicin, Menthol and Lidocaine Hydrochloride. Medical records document the long-term use of NSAID medications, which is not recommended by MTUS guidelines. MTUS guidelines and medical records do not support the use of the NSAIDs. Methyl salicylate is a NSAID. There is no documentation that the patient has not responded or is intolerant to other treatments. This is a requirement for the use of topical Capsaicin. There was no documentation of post-herpetic neuralgia. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. Medical records do not document a diagnosis of post-herpetic neuralgia, which is the only FDA approved indication for topical Lidocaine. The use of topical Lidocaine is not supported. Per MTUS guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS guidelines and medical records do not support the medical necessity of topical Lidocaine, Capsaicin, or Methyl Salicylate, which are active ingredients in Terocin. Therefore, the request for Terocin 240 Dos 7/22/2013 is not medically necessary.