

Case Number:	CM14-0133624		
Date Assigned:	08/27/2014	Date of Injury:	02/08/2007
Decision Date:	10/02/2014	UR Denial Date:	08/13/2014
Priority:	Standard	Application Received:	08/21/2014

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 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 with bilateral shoulder conditions status post right shoulder arthroscopic rotator cuff repair surgery 4/20/12. Mechanism of injury was lifting a bag. Date of injury was 02-08-2007. Progress report dated 7/24/14 documented subjective complaints of bilateral shoulder pain. Medications included Ibuprofen and Tylenol #3. The patient was also receiving physical therapy and Terocin patches. Physical examination findings included cervical and lumbar spine full range of motion. Bilateral shoulders had tenderness and decreased range of motion. Diagnosis was disorders of bursae and tendons in the shoulder region. Treatment plan included Terocin patch. Utilization review determination date was 8/13/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Patch, #10: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics , Capsaicin, topical Page(s): 111-113, 28-29. Decision based on Non-MTUS Citation NSAIDs Page 69-70 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 do not present blood pressure measurements or laboratory test results, which are recommended for NSAID use per MTUS. Medical records indicate long-term NSAID use, which is not recommended by MTUS. Methyl salicylate is a NSAID. The patient is concurrently taking Ibuprofen which is an NSAID. Thus Methyl salicylate is a redundant NSAID. The patient has also been prescribed Tylenol #3. 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. 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 Patch, #10 not medically necessary.