

Case Number:	CM15-0064845		
Date Assigned:	04/10/2015	Date of Injury:	09/02/1999
Decision Date:	05/18/2015	UR Denial Date:	04/02/2015
Priority:	Standard	Application Received:	04/06/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Internal Medicine

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 injured worker is a 52 year old male, who sustained an industrial injury on 9/2/1999. The current diagnoses are lumbar disc herniation, status post fusion at L4-5 and L5-S1, and chronic pain. According to the progress report dated 3/2/2015, the injured worker complains of persistent low back pain. He describes his pain as a constant ache, which is worse in the mornings. The pain is rated 7/10 on a subjective pain scale. The current medications are Tramadol. Treatment to date has included medication management, MRI studies, acupuncture, home exercise program, and surgical intervention. The plan of care includes Lidopro topical ointment, prescription refill for Tramadol, and follow-up in three months.

IMR ISSUES, DECISIONS AND RATIONALES

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

One prescription of Lidopro Topical Ointment: 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 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Capsaicin, topical Page 28-29.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address 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. 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. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, 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. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count 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. 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. Capsaicin is only an option in patients who have not responded or are intolerant to other treatments. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. LidoPro contains capsaicin, lidocaine, menthol, and methyl salicylate. The primary treating physician's progress report dated 3/2/15 documented that patient was taking Aleve but was diagnosed with an ulcer. Per MTUS, NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Per MTUS, topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Medical records indicate the long- term use of NSAIDS. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Medical records indicate long-term NSAID use, which is not recommended by MTUS. Methyl salicylate, a component of LidoPro, 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 per MTUS. There was no documentation of post-herpetic neuralgia. Per MTUS, 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. MTUS guidelines and medical records do not support the medical necessity of a topical analgesic containing Methyl Salicylate, Capsaicin, and Lidocaine, which are ingredients in LidoPro. Per MTUS guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for Lidopro topical ointment is not medically necessary.