

Case Number:	CM15-0039261		
Date Assigned:	03/09/2015	Date of Injury:	06/09/2011
Decision Date:	06/30/2015	UR Denial Date:	02/05/2015
Priority:	Standard	Application Received:	03/02/2015

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 60 year old male, who sustained an industrial injury on 6/9/11. He has reported initial complaints of a pop in the left shoulder followed by increased pain and low back pain after lifting a large television. The diagnoses have included status post left shoulder arthroscopy surgery with residual pain, left shoulder tendinosis/impingement, lumbosacral sprain/strain, chronic cervical pain, and history of hypertension, diabetes, coronary artery disease and gastric ulcer disease. Treatment to date has included medications, diagnostics, labs, chiropractic, physical therapy, psychiatric care, pain management and home exercise program (HEP). Currently, as per the physician progress note dated 1/16/15, the injured worker complains of continued neck, shoulder and low back pain. The physical exam reveals spasm and tenderness over the cervical spine. There is limited range of motion in the left shoulder. The current medications included Norco and Tramadol for severe and moderate pain. The labs obtained to assess for medication compliance dated 9/18/14 and 11/17/14 were inconsistent with the medications prescribed. Treatment plan was for medications and to return in 1 month. The physician requested treatments included Retrospective: Terocin pain Patch #20 and Retrospective: Methoderm Gel 120mg #1.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective: Terocin pain Patch #20: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Capsaicin, topical Page 28-29. 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 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. 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. Capsaicin is only an option in patients who have not responded or are intolerant to other treatments. 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. All NSAIDs have the potential to raise blood pressure in susceptible patients. 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. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) indicates that non-steroidal anti-inflammatory drugs (NSAID) can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. Terocin is a topical analgesic, containing methyl salicylate, capsaicin, menthol and lidocaine hydrochloride. The pain management report dated

September 18, 2014 documented a history of diabetes, acid reflux, hypertension, hypercholesterolemia, two esophageal procedures 2014, gastric ulcers, and coronary artery disease. The patient was hospitalized for angina 2004 and hospitalized for bleeding ulcers 2007. Medications included Hydrochlorothiazide, Lisinopril, Enalapril, and Metoprolol. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. Per MTUS, NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Given the patient's history of hypertension, coronary artery disease, and gastric ulcers, the use of NSAID medications is not recommended. Methyl salicylate is a non-steroidal anti-inflammatory drug. 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. There is no documentation that the patient has not responded or is intolerant to other treatments. Per MTUS, this is a requirement for the use of topical Capsaicin. 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 Terocin is not supported by MTUS guidelines. Therefore, the request for Terocin is not medically necessary.

Retrospective: Mentherm Gel 120mg #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Decision based on Non-MTUS Citation Mentherm <http://www.physiciansproducts.net/product/mentherm/> <http://www.drugs.com/cdi/mentherm-cream.html>.

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. All NSAIDs have the potential to raise blood pressure in susceptible patients. 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. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) indicates that non-steroidal anti-inflammatory drugs (NSAID) can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. Menthoderm contains Methyl Salicylate (NSAID) and Menthol. The pain management report dated September 18, 2014 documented a history of diabetes, acid reflux, hypertension, hypercholesterolemia, two esophageal procedures 2014, gastric ulcers, and coronary artery disease. The patient was hospitalized for angina 2004 and hospitalized for bleeding ulcers 2007. Medications included Hydrochlorothiazide, Lisinopril, Enalapril, and Metoprolol. Per MTUS, NSAIDS are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. Per MTUS, NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Given the patient's history of hypertension, coronary artery disease, and gastric ulcers, the use of NSAID medications is not recommended. Methyl salicylate is a non-steroidal anti-inflammatory drugs. 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 Menthoderm is not supported by MTUS guidelines. Therefore, the request for Menthoderm is not medically necessary.