

<b>Case Number:</b>	CM15-0032159		
<b>Date Assigned:</b>	02/25/2015	<b>Date of Injury:</b>	03/08/2012
<b>Decision Date:</b>	04/13/2015	<b>UR Denial Date:</b>	01/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/20/2015

### 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 51 year old male, who sustained an industrial injury on 3/8/2012. The current diagnoses are discogenic cervical condition with facet inflammation and shoulder girdle involvement, headaches, discogenic lumbar condition with facet inflammation, and possible knee derangement with some instability along the anterior cruciate ligament. Currently, the injured worker complains of neck, low back, and right knee pain. The physical examination of the cervical spine reveals tenderness along the facets. Facet loading is positive. There is limited range of motion of the cervical and lumbar spine. In the knees, there is minimal discomfort and some tenderness along the joint lines noted. The treating physician is requesting retrospective LidoPro cream one bottle, Terocin Patches #20, and TENS unit and conductive garment purchase (DOS 12/17/14), which is now under review. On 1/21/2015, Utilization Review had non-certified a request for retrospective LidoPro cream one bottle, Terocin Patches #20, and TENS unit and conductive garment purchase (DOS 12/17/14). The TENS unit was modified to a one month trial. The California MTUS Chronic Pain Medical Treatment Guidelines were cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**LidoPro Cream one bottle Date of Service: 12/17/14: Upheld**

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

**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. LidoPro contains capsaicin, lidocaine, menthol, and methyl salicylate. 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 cream is not medically necessary.

**Terocin Patches #20 Date of Service: 12/17/14: Upheld**

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

**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 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. 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. Capsaicin is only an option in patients who have not responded or are intolerant to other treatments. Terocin is a topical analgesic, containing methyl salicylate, capsaicin, menthol and lidocaine hydrochloride. 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. Methyl salicylate is a NSAID. 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 TENS unit purchase and conductive garment purchase (DOS 12/17/2014):**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints, Chapter 8 Neck and Upper Back Complaints Page(s): 173-174, 181-183, 300, 308-310, 339, 346-347. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back (Acute & Chronic) Electrotherapies. ACOEM 3rd Edition - Knee disorders <http://www.guideline.gov/content.aspx?id=36632> Work Loss Data Institute - Neck and upper back (acute & chronic) <http://www.guideline.gov/content.aspx?id=47589>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) addresses transcutaneous electrotherapy. MTUS Chronic Pain Medical Treatment Guidelines indicates that several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 12 Low Back Complaints (Page 300) states that physical modalities such as diathermy, ultrasound, transcutaneous electrical neurostimulation (TENS) units, percutaneous electrical nerve stimulation (PENS) units, and biofeedback have no proven efficacy in treating acute low back symptoms. Insufficient scientific testing exists to determine the effectiveness of these therapies. Table 12-8 Summary of Recommendations for Evaluating and Managing Low Back Complaints (Page 308) states that TENS is not recommended. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 13 Knee Complaints (Page 339) states that physical modalities, such as massage, diathermy, cutaneous laser treatment, ultrasound, and biofeedback have no scientifically proven efficacy in treating acute knee symptoms. Other miscellaneous therapies have been evaluated and found to be ineffective. Table 13-6 Summary of Recommendations for Evaluating and Managing Knee Complaints (Page 346-347) indicates that regarding physical treatment methods, passive modalities without exercise program are not recommended. ACOEM 3rd Edition does not recommend transcutaneous electrical stimulation (TENS) for knee pain. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 8 Neck and Upper Back Complaints Table 8-8 Summary of Recommendations for Evaluating and Managing Neck and Upper Back Complaints (Page 181-183) states that TENS is not recommended. ACOEM Chapter 8 (Page 173-174) states that there is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as traction, heat / cold applications, massage, diathermy, cutaneous laser treatment, ultrasound, transcutaneous electrical neuro-stimulation (TENS) units, and biofeedback. Official Disability Guidelines (ODG) Neck and Upper Back (Acute & Chronic) state that electrotherapies are not

recommended. Work Loss Data Institute guidelines for Neck and Upper Back (acute & chronic) state that electrotherapies are not recommended. The medical records document a history of neck, back, and knee complaints. MTUS, ACOEM, ODG, and Work Loss Data Institute guidelines and medical records do not support the use of transcutaneous electrical nerve stimulation (TENS). Therefore, the request for transcutaneous electrical nerve stimulation (TENS) is not medically necessary.