

<b>Case Number:</b>	CM15-0223702		
<b>Date Assigned:</b>	11/19/2015	<b>Date of Injury:</b>	05/14/2013
<b>Decision Date:</b>	12/30/2015	<b>UR Denial Date:</b>	10/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/13/2015

### 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, Indiana, New York  
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 53 year old male, who sustained an industrial injury on 5-14-13. The documentation on 9-15-15 noted that the injured worker has complaints of right knee pain that has been catching since 4-8-15 and worsening since early August. Examination of the right knee revealed positive locking noted on the right knee during weight bearing ambulation as well as passive and active range of motion. Positive McMurray's test noted and there is positive tenderness on palpation to the medial joint line. The diagnoses have included right knee medial meniscus tear and status post failed anterior cruciate ligament repair in the right knee. Treatment to date has included cortisone injection; anti-inflammatory and topical cream. The original utilization review (10-16-15) non-certified the request for pain cream (flurbiprofen-baclofen-cyclobenzaprine-gabapentin-lidocaine) quantity 1.00 pain spray (lidocaine-menthol) quantity one.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pain cream (Flurbiprofen/Baclofen/Cyclobenzaprine/Gabapentin/Lidocaine) Qty 1.00:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Topical analgesics.

**Decision rationale:** Pursuant to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, pain cream (flurbiprofen, baclofen, cyclobenzaprine, gabapentin, and lidocaine) #1 is not medically necessary. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Other than Lidoderm, no other commercially approved topical formulation of lidocaine whether cream, lotions or gels are indicated for neuropathic pain. In this case, the injured worker's working diagnoses are right knee medial meniscus tear; and status post failed anterior cruciate ligament repair right knee. Date of injury is May 14, 2013. Request for authorization is October 13 2015. According to September 15, 2015, progress note, subjective complaints are ongoing right knee pain. Objectively, there is positive McMurray's and tenderness over the medial joint line to palpation. Flurbiprofen is not FDA approved for topical use. Baclofen topical is not recommended. Cyclobenzaprine topical is not recommended. Gabapentin topical is not recommended. Lidocaine in non-Lidoderm form is not recommended. Any compounded product that contains at least one drug (Flurbiprofen, baclofen, cyclobenzaprine, gabapentin and lidocaine and non-Lidoderm form) that is not recommended is not recommended. Consequently, pain cream (Flurbiprofen, baclofen, cyclobenzaprine, gabapentin, and lidocaine) #1 is not recommended. Based on the clinical information in the medical record and the peer-reviewed evidence-based guidelines, pain cream (flurbiprofen, baclofen, cyclobenzaprine, gabapentin, and lidocaine) #1 is not medically necessary.

**Pain spray (Lidocaine/Menthol) Qty 1.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/1441878>.

**Decision rationale:** Pursuant to the PubMed.gov, pain spray (lidocaine, menthol) #1 is not medically necessary. Lidocaine is often used as a topical analgesic prior to painful procedures performed in the oral cavity and upper airways. In this study, the optimal time interval for performance of painful procedures in the oral cavity and the upper airways was determined by spraying lidocaine solution on the mucous membranes of the mouth with subsequent measurements of pain thresholds induced by argon-laser stimulation. Two different dosages (30 mg and 60 mg) of lidocaine spray were administered to the oral mucosa of the lower lip in healthy volunteers. Repeated measurements were performed until normal sensitivity returned after 15 min. Pain thresholds increased 62% after 30 mg lidocaine and 50% after 60 mg lidocaine

(a non-significant difference). Thus, repeated applications were found to be without any additional hypoalgesic effect. Maximal hypoalgesia was reached after 4 to 5 min. Complete analgesia was not obtained. The hypoalgesic effect lasted until 14 min, but painful procedures should be performed in the time interval 3-8 min after application. Topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Other than Lidoderm, no other commercially approved topical formulation of lidocaine whether cream, lotions or gels are indicated for neuropathic pain. In this case, the injured worker's working diagnoses are right knee medial meniscus tear; and status post failed anterior cruciate ligament repair right knee. Date of injury is May 14, 2013. Request for authorization is October 13 2015. According to September 15, 2015, progress note, subjective complaints are ongoing right knee pain. Objectively, there is positive McMurray's and tenderness over the medial joint line to palpation. Lidocaine is often used as a topical analgesic prior to painful procedures performed in the oral cavity and upper airways. In this study the optimal time interval for performance of painful procedures in the oral cavity and the upper airways was determined by spraying lidocaine solution on the mucous membranes of the mouth with subsequent measurements of pain thresholds induced by argon-laser stimulation. The directions for use include the sublingual administration of the lidocaine and menthol spray. There are no painful oral maladies noted in the medical record to be addressed with a sublingual lidocaine and menthol spray. There is no documentation of failed first-line treatment with antidepressants and anticonvulsants. Topical analgesics are largely experimental with few controlled trials. There is no clinical indication or rationale for a sublingual lidocaine, menthol spray. Based on the clinical information the medical record, peer-reviewed evidence-based guidelines, guideline on recommendations for a sublingual lidocaine, menthol spray, no documentation of intraoral painful areas, pain spray (lidocaine, menthol) #1 is not medically necessary.