

<b>Case Number:</b>	CM15-0141267		
<b>Date Assigned:</b>	07/31/2015	<b>Date of Injury:</b>	04/03/2013
<b>Decision Date:</b>	09/25/2015	<b>UR Denial Date:</b>	07/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/21/2015

### 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: Physical Medicine & Rehabilitation

### 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 59 year old male, who sustained an industrial injury on April 3, 2013 while working as a laborer. The mechanism of injury was a slip and fall in which the injured worker landed hard on his right buttock. The injured worker experienced right-sided low back pain with radiation into the right leg. The diagnoses have included chronic lumbar strain, lumbar intermittent right lower extremity radiculitis, lumbar spasm, lumbosacral degenerative disc disease, mild multilevel degenerative joint disease and bilateral hip osteoarthritis. Treatment and evaluation to date has included medications, radiological studies, home exercise program and physical therapy. The injured worker was noted to be working with modified duties. Current documentation dated June 10, 2015 notes that the injured worker reported diffuse low back pain with intermittent radiation to the right posterior hip and thigh, unchanged from the previous visit. Examination of the lumbar spine revealed diffuse tenderness, no palpable spasm and a positive FABER (flexion, abduction and external rotation) test. Range of motion showed flexion to be 70 degrees and extension 15 degrees. A sitting straight leg raise test was mildly positive on the right. The treating physician's plan of care included a request for the compound cream: Flurbiprofen 20%, Cyclobenzaprine 4% and Lidocaine 5%.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%, Cyclobenzaprine 4%, Lidocaine 5%: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA.

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

**Decision rationale:** Based on the 5/13/15 progress report provided by the treating physician, this patient presents with low back pain, right > left, radiating into the right leg. The treater has asked for Flurbiprofen 20%, Cyclobenzaprine 4%, Lidocaine 5% but the requesting progress report is not included in the provided documentation. The request for authorization was not included in provided reports. The patient states that walking causes pain in the right hip and right side of lower back, and symptoms are relieved by medication and rest per 5/13/15 report. The patient is s/p left knee surgery from 2012, unspecified per 5/13/15 report. The patient is currently taking Naproxen per 5/13/15 report. The patient is currently wearing a corset brace that is helpfully somewhat per 5/13/15 report. The patient is currently not working per 5/13/15 report. MTUS, Topical Analgesics section, pg. 111: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, "-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists", agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. MTUS, Topical Analgesics, pg. 113: Gabapentin: Not recommended. There is no peer-reviewed literature to support use. MTUS, Topical Analgesics section under Lidocaine, pg. 112: Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. The patient has not had prior use of this requested topical medication per review of reports. The treater does not discuss this request in the reports provided. The treater does not explain why this topical formulation was chosen and how and where it will be used. MTUS Guidelines also provide clear discussion regarding topical compounded creams on pg 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The cream contains Gabapentin and Lidocaine which are not recommended by MTUS; therefore the entire compounded cream is not medically necessary.