

<b>Case Number:</b>	CM15-0113933		
<b>Date Assigned:</b>	06/22/2015	<b>Date of Injury:</b>	11/15/2013
<b>Decision Date:</b>	07/22/2015	<b>UR Denial Date:</b>	05/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/12/2015

### 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: Emergency 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 (IW) is a 38-year-old male who sustained an industrial injury on 11/15/2013. Diagnoses include lumbar sprain/strain and lumbar radiculopathy. Treatment to date has included medications, physical therapy, acupuncture and home exercise program. According to the progress notes dated 4/9/15, the IW reported intermittent moderate, sharp low back pain and stiffness with numbness and tingling rated 5/10. Prolonged standing, walking and sitting, aggravated pain. On examination, range of motion of the lumbar spine was decreased and painful. Flexion was 40/60 degrees, extension 20/25 degrees, left lateral bending 10/25 degrees and right lateral bending 15/25 degrees, which was slightly improved from his 1/7/15 office visit exam. The bilateral sacroiliac joints, coccyx, lumbar paravertebral muscles and sacrum were all tender to palpation and muscle spasms were present in the bilateral gluteal muscles and the lumbar paravertebral muscles. Electrodiagnostic testing on 9/17/14 found mild prolonged H-reflex, possibly secondary to metabolic disorders versus S1 radiculopathy; correlation with imaging was recommended. MRI of the lumbar spine on 3/6/14 was noted as essentially unremarkable except for minimal degenerative osteophytosis throughout the lumbar spine. A request was made for compound FBD - Flurbiprofen 20%/Baclofen 5%/Dexamethasone 2%/Menthol 2%/Capsaicin 0.025% in cream base - 210gm.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%/Baclofen 5%/Dexamethasone 2%/Menthol 2%/Capsaicin 0.025% in cream base 210 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113.

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

**Decision rationale:** As per MTUS guidelines, "Any compound product that contains a drug or drug class that is not recommended is not recommended." 1) Flurbiprofen: Topical NSAIDs are shown to be superior to placebo. It should not be used long term. It may be useful. Flurbiprofen is not FDA approved for topical application. There is no justification by the provider as to why the patient requires a non-FDA approved compounded NSAID when there are multiple other approved products including over the counter medications on the market. Flurbiprofen is not medically necessary. 2) Baclofen is not FDA approved for topical use. There is no evidence for efficacy as a topical product. 3) Dexamethasone is a steroid. It is not clear how a topical steroid is useful for patient's pathology. 4) Capsaicin: Data shows efficacy in muscular skeletal pain and may be considered if conventional therapy is ineffective. There is no documentation of treatment failure or a prior successful trial of capsaicin. It is not recommended. This non-evidence based compounded product with multiple non-FDA approved substances is not medically necessary.