

<b>Case Number:</b>	CM15-0168616		
<b>Date Assigned:</b>	09/15/2015	<b>Date of Injury:</b>	06/03/2014
<b>Decision Date:</b>	10/20/2015	<b>UR Denial Date:</b>	07/31/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/27/2015

### 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 is a 47 year old male, who sustained an industrial injury on 6-3-2014. Medical records indicate the worker is undergoing treatment for thoracic and lumbar sprain-strain. A recent progress report dated 7-23-2015, reported the injured worker complained of occasional upper mid back pain stiffness and numbness associated with movement and lifting and low back pain with burning, stiffness, numbness and stiffness, rated 8 out of 10. Pain relief was noted from medications and massage. Physical examination revealed lumbar 3-5 tenderness. Treatment to date has included physical therapy, Diclofenac sodium, Pantoprazole, Orphenadrine, Alprazolam and Zolpidem. The physician is requesting Flurbiprofen 20%-Baclofen 5%-Dexamethasone 2%-Menthol 2%-Camphor 2%-Capsaicin 0.025% 240 grams and Amitriptyline 10%-Gabapentin 10%-Bupivacaine 5%-Hyaluronic Acid 0.2% 240 grams. On 7-31-2015, the Utilization Review Flurbiprofen 20%-Baclofen 5%-Dexamethasone 2%-Menthol 2%-Camphor 2%-Capsaicin 0.025% 240 grams and Amitriptyline 10%-Gabapentin 10%-Bupivacaine 5%-Hyaluronic Acid 0.2% 240 grams

### 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%/Camphor 2%/Capsaicin 0.025% 240 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** The requested product is a compounded cream composed of multiple medications. As per MTUS guidelines, "Any compounded product that contain one drug or drug class that is not recommended is not recommended." 1) Flurbiprofen: Not Recommended. A topical NSAID that may be used short term for musculoskeletal pain. Flurbiprofen is not FDA approved for topical application. It is not clear why this was prescribed when multiple FDA approved topical NSAIDs are available. 2) Baclofen: This is a muscle relaxant. It is not FDA approved for topical use. There is no evidence to support topical use of this medication. 3) Dexamethasone: Not recommended. Dexamethasone is a steroid. There is no information available in MTUS Chronic pain or ACOEM guidelines concerning topical use of steroids for musculoskeletal pains. Review of Official Disability Guide and ACOEM guidelines only mention use of systemic and injectable steroid. There is a significant risk of systemic absorption and side effects. 4) Camphor/Menthol: May have some topical soothing ability. 5) Capsaicin: Not recommended. 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 successful trial of capsaicin. This compounded cream has multiple non-evidence based medications with potentially severe side effects and toxicity. This cream is not medically appropriate or necessary.

**Amitriptyline 10%/Gabapentin 10%/Bupivacaine 5%/Hyaluronic Acid 0.2% 240 grams:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** The requested product is a compounded cream composed of multiple medications. As per MTUS guidelines, "Any compounded product that contain one drug or drug class that is not recommended is not recommended." Amitriptyline and gabapentin are medications used for treatment of nerve pain; none of these meds are FDA approved for topical use. Bupivacaine is an anesthetic, only topical lidocaine is approved for neuropathic pain. Bupivacaine is only approved for injection for local or regional anesthesia. Hyaluronic acid is only approved for injection or oral use, there is no evidence to support topical use. Use of a non-FDA approved product for unknown purpose is not recommended. Not a single component in this compounded is supported by scientific evidence or guidelines. This evidence based compounded substance is not medically necessary and completely inappropriate.