

<b>Case Number:</b>	CM15-0160911		
<b>Date Assigned:</b>	08/27/2015	<b>Date of Injury:</b>	04/10/2004
<b>Decision Date:</b>	09/30/2015	<b>UR Denial Date:</b>	07/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/17/2015

### 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 42 year old male, who sustained an industrial injury on April 10, 2004. Treatment to date has included diagnostic imaging, EMG-NCV of the bilateral lower extremities, physical therapy and pain medications. Currently, the injured worker complains of constant low back pain with radiation of pain to the bilateral lower extremities. He reports that the pain radiates to the bilateral buttocks and he has constant numbness in the bilateral lower extremities to the level of the knees. He describes his pain as severe aching and throbbing. He has moderate difficulty with sleep, moderate gastrointestinal upset, bowel dysfunction and diarrhea. He reports limitations with self-care, hygiene, activity, ambulation and sleep due to pain. He rates his pain a 3 on a 10-point scale with medications and an 8 on a 10-point scale without medications. His pain is improved with bedrest and relaxation. On physical examination, the injured worker has tenderness to palpation over the L4-S1 levels and limited lumbar range of motion. His pain increased significantly with flexion and extension. He has a normal sensory examination and he has a negative straight leg raise. The diagnoses associated with the request include chronic pain syndrome, lumbar facet arthropathy, lumbar radiculitis, and status post lumbar spine artificial disc placement of L4-S1. The treatment plan includes flurbiprofen-capsaicin 10% - 0.025% cream and lidocaine-gabapentin 5%-10% gel for pain.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen/Capsaicin (plain) 10%/0.025% cream #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Compounding Medications Page(s): 71.

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

**Decision rationale:** The patient presents with constant pain in the mid and low back radiating into the lower extremities rated 8/10. The request is for FLURBIPROFEN/CAPSAICIN (PLAIN) 10%/0.025% CREAM #120. The request for authorization is not provided. The patient is status post L3 through S1 total disc replacement, date unspecified. EMG/NCS of the lower extremity, 05/15/15, shows normal study. CT Scan of the lumbar spine, 05/13/15, shows metallic interbody disc apparatus at L3-L4, L4-L5, and L5-S1; these appear in satisfactory position and the integrity appears maintained; no abnormalities are noted. Physical examination of the thoracolumbar spine reveals tenderness from the thoracic to lumbar segments with spasm. Seated nerve root test is positive. There is pain with terminal motion with limited range of motion. There is dysesthesia at the L5-S1 dermatome. Per progress report dated 05/05/15, the patient is permanently partially disabled. MTUS has the following regarding topical creams, Chronic Pain Section, p 111: "Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. 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. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Treater does not specifically discuss this medication. Prescription history for this compounded topical cream is not provided. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the patient continues with pain in the mid and low back radiating into the lower extremities. The treater does not document or discuss this patient presenting with arthritis/tendinitis for which the Flurbiprofen component of this topical medication would be indicated. Therefore, the request IS NOT medically necessary.

**Lidocaine/Gabapentin 5%, 10% gel #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Compounding Medications Page(s): 71.

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

**Decision rationale:** The patient presents with constant pain in the mid and low back radiating into the lower extremities rated 8/10. The request is for LIDOCAINE/GABAPENTIN 5%, 10% GEL #120. The request for authorization is not provided. The patient is status post L3 through S1 total disc replacement, date unspecified. EMG/NCS of the lower extremity, 05/15/15, shows normal study. CT Scan of the lumbar spine, 05/13/15, shows metallic interbody disc apparatus at L3-L4, L4-L5, and L5-S1; these appear in satisfactory position and the integrity appears maintained; no abnormalities are noted. Physical examination of the thoracolumbar spine reveals tenderness from the thoracic to lumbar segments with spasm. Seated nerve root test is positive. There is pain with terminal motion with limited range of motion. There is dysesthesias at the L5-S1 dermatome. Per progress report dated 05/05/15, the patient is permanently partially disabled. MTUS has the following regarding topical creams, Chronic Pain Section, p 111: "Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. 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. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Treater does not specifically discuss this medication. Prescription history for this compounded topical cream is not provided. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound contains Gabapentin, which is not supported for topical use. Additionally, this topical cream contains Lidocaine, and MTUS does not support any formulation of Lidocaine other than a patch. Therefore, the request IS NOT medically necessary.