

<b>Case Number:</b>	CM15-0174212		
<b>Date Assigned:</b>	09/24/2015	<b>Date of Injury:</b>	07/15/2011
<b>Decision Date:</b>	11/18/2015	<b>UR Denial Date:</b>	08/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/03/2015

### 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 53 year old female with a date of injury on 07-15-2011. The injured worker is undergoing treatment for chronic left lateral epicondylitis, status post release of the common extensor origin on 04-17-2015. A physician progress note dated 07-20-2015 documents the injured worker is improving but still had some complaints of pain with extension of her fingers, wrist and forearm in general. Motor tone and sensation is intact. Incision is clean and intact. Treatment to date has included diagnostic studies, medications, 4 injections to the left elbow, 12 physical therapy sessions, and release of common extensor origin of the left elbow on 04-17-2015. The treatment plan includes physical therapy right elbow 3 times a week for 4 weeks-12 sessions, and anti-inflammatory pain cream. With her next visit she most likely can be given a permanent and stationary status and a possible trial return to full job duties, depending on how she responds. On 08-16-2015 the Utilization Review non-certified the requests for Flurbiprofen 15%-Cyclobenzaprine 3%-Capsaicin 0.0375%- Menthol 2%-Camphor 1% 120gm ordered 7-20-15, Flurbiprofen 15%-Cyclobenzaprine 3%-Capsaicin 0.0375%- Menthol 2%-Camphor 1% 30gm ordered 7-20-15, Flurbiprofen 20% 120gm ordered 7-20-15, and Flurbiprofen 20% 30gm ordered 7-20-15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 15%/Cyclobenzaprine 3%/Capsaicin 0.0375%/ Menthol 2%/Camphor 1% 30gm ordered 7/20/15: 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 request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following regarding muscle relaxants used topically: Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. As indicated above, due to inadequate clinical evidence of efficacy, the request is not medically necessary.

**Flurbiprofen 20% 30gm ordered 7/20/15: 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 request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine,

hip or shoulder. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the treatment duration. As such, the request is not medically necessary.

**Flurbiprofen 15%/Cyclobenzaprine 3%/Capsaicin 0.0375%/ Menthol 2%/Camphor 1% 120gm ordered 7/20/15: 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 request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following regarding muscle relaxants used topically: Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. As indicated above, due to inadequate clinical evidence of efficacy, the request is not medically necessary.

**Flurbiprofen 20% 120gm ordered 7/20/15: 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 request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for

short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the treatment duration. As such, the request is not medically necessary.