

<b>Case Number:</b>	CM15-0195254		
<b>Date Assigned:</b>	10/09/2015	<b>Date of Injury:</b>	12/19/2013
<b>Decision Date:</b>	11/25/2015	<b>UR Denial Date:</b>	09/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/05/2015

### 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 29-year-old male, with a reported date of injury of 12-19-2013. The diagnoses include chronic right thigh contusion, chronic low back strain, and probable right hip contusion with possible trochanteric bursitis on the right. Treatments and evaluation to date have included medical marijuana, Clinoril, Norco, and physical therapy for the right hip and pelvis. The diagnostic studies to date have included an x-ray of the right hip on 02-06-2014 with negative findings; an x-ray of the pelvis on 02-06-2014 with negative findings; an MRI of the right thigh on 02-11-2015 with negative findings; an MRI of the lumbar spine on 04-17-2015 which showed degenerative changes at L3-4; and an MRI of the right hip on 04-17-2015 which showed mild asphericity of the femoral head neck junctions bilaterally, fraying of the right foveal ligament tear, and mild tendinosis. The orthopedic progress report dated 09-17-2015 indicates that the injured worker continued to have right lateral thigh pain and occasional swelling in the area of his previous trauma. There was no radiation of pain down the leg, and no numbness or weakness reported. The physical examination showed a slight Trendelenburg gait of the right hip; equal bilateral hip range of motion; tenderness to palpation about the soft tissues at the posterolateral aspect of the hip where there was a palpable fluid collection and a Morel lesion of the soft tissue still present; no signs of infection; a 2+ dorsalis pedis pulse; and normal sensation to light touch distally. The treatment plan included the consideration of topical anti-inflammatory medications. The injured worker's work status was not indicated. The progress report dated 07-23-2015 indicates that the injured worker reported that physical therapy helped; however, he still had some symptoms of the hip to report. There was soreness at

the posterolateral aspect where he had a soft tissue defect. The treatment plan included a starter pack of compounded medications. The treating physician felt that the injured worker "would be a good candidate for transdermal cream". A thin layer of the medications were to be applied to the affected area two to three times a day. The treating physician requested Cyclobenzaprine 10%-Lidocaine 2% 150 grams; Flurbiprofen 20%-Lidocaine 5% 150 grams; and Gabapentin 10%-Amitriptyline 5%-Capsaicin 0.025% 150 grams. On 09-30-2015, Utilization Review (UR) non-certified the request Cyclobenzaprine 10%-Lidocaine 2% 150 grams; Flurbiprofen 20%-Lidocaine 5% 150 grams; and Gabapentin 10%-Amitriptyline 5%-Capsaicin 0.025% 150 grams.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 prescription of Cyclobenzaprine 10%/Lidocaine 2% 150gm: Upheld**

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

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

**Decision rationale:** Based on the 08/14/15 progress report provided by treating physician, the patient presents with pain and swelling to the right lateral thigh. The request is for 1 prescription of cyclobenzaprine 10%/lidocaine 2% 150GM. RFA dated 09/17/15 provided. Patient's diagnosis on 08/14/15 includes chronic right thigh contusion with soft tissue swelling, chronic low back pain, probable right hip contusion with trochanteric bursitis on the right, and persistent swelling of the right posterolateral thigh area. Physical examination on 09/17/15 revealed a slight Trendelenburg gait of the right hip; equal bilateral hip range of motion; tenderness to palpation about the soft tissues at the posterolateral aspect of the hip where there was a palpable fluid collection and a Morel lesion of the soft tissue still present; and 2+ dorsalis pedis pulse. Treatment to date has included imaging studies, physical therapy and medications. The patient is prescribed Norco. Treater states the patient is "not able to work as a construction worker," per 08/14/15 report. MTUS, Topical Analgesics section, page 111 has the following: "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... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." "Topical Analgesics: Non-steroidal antiinflammatory 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. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. 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 has not provided medical rationale for the request, nor indicated where this topical is applied and with what efficacy. Nonetheless, MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. In this case, the requested topical compound contains Cyclobenzaprine and Lidocaine, which are not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request IS NOT medically necessary.

**1 prescription of Flurbiprofen 20%/ Lidocaine 5% 150gm: Upheld**

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

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

**Decision rationale:** Based on the 08/14/15 progress report provided by treating physician, the patient presents with pain and swelling to the right lateral thigh. The request is for 1 prescription of flurbiprofen 20%/ lidocaine 5% 150gm. Patient's diagnosis on 08/14/15 includes chronic right thigh contusion with soft tissue swelling, chronic low back pain, probable right hip contusion with trochanteric bursitis on the right, and persistent swelling of the right posterolateral thigh area. Physical examination on 09/17/15 revealed a slight Trendelenburg gait of the right hip; equal bilateral hip range of motion; tenderness to palpation about the soft tissues at the posterolateral aspect of the hip where there was a palpable fluid collection and a Morel lesion of the soft tissue still present; and 2+ dorsalis pedis pulse. Treatment to date has included imaging studies, physical therapy and medications. The patient is prescribed Norco. Treater states the patient is "not able to work as a construction worker," per 08/14/15 report. MTUS, Topical Analgesics section, page 111 has the following: "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... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Topical Analgesics: Non-steroidal antiinflammatory 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. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. 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 has not provided medical rationale for the request, nor indicated where this topical is applied and with what efficacy. Nonetheless, MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. In this case, the requested topical compound contains Lidocaine, which is not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request IS NOT medically necessary.

**Gabapentin 10%/ Amitriptyline 5%/ Capsaicin 0.025% 150gm:** Upheld

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

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

**Decision rationale:** Based on the 08/14/15 progress report provided by treating physician, the patient presents with pain and swelling to the right lateral thigh. The request is for gabapentin 10%/ amitriptyline 5%/ capsaicin 0.025% 150gm. Patient's diagnosis on 08/14/15 includes chronic right thigh contusion with soft tissue swelling, chronic low back pain, probable right hip contusion with trochanteric bursitis on the right, and persistent swelling of the right posterolateral thigh area. Physical examination on 09/17/15 revealed a slight Trendelenburg gait of the right hip; equal bilateral hip range of motion; tenderness to palpation about the soft tissues at the posterolateral aspect of the hip where there was a palpable fluid collection and a Morel lesion of the soft tissue still present; and 2+ dorsalis pedis pulse. Treatment to date has included imaging studies, physical therapy and medications. The patient is prescribed Norco. Treater states the patient is "not able to work as a construction worker," per 08/14/15 report. MTUS, Topical Analgesics section, page 111 has the following: "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... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Topical Analgesics: Non-steroidal antiinflammatory 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. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. 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 has not provided medical rationale for the request, nor indicated where this topical is applied and with what efficacy. Nonetheless, 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 in lotion form, per MTUS. Furthermore, there is no support for anti-depressants such as Amitriptyline in MTUS nor ODG for topical use. This request is not in accordance with guidelines. Therefore, the request IS NOT medically necessary.