

<b>Case Number:</b>	CM14-0029904		
<b>Date Assigned:</b>	06/20/2014	<b>Date of Injury:</b>	01/29/2013
<b>Decision Date:</b>	10/10/2014	<b>UR Denial Date:</b>	02/10/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/10/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Oklahoma. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations

### 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 51 year old male who reported an injury on 1/29/2013. The mechanism of injury occurred due to a fall. His diagnoses consisted of a right knee medial tear with lateral meniscus tear to the right knee patella and right hip joint effusion. The injured worker's past treatments included medication, topical creams, injections, and approximately 8 sessions of acupuncture. His diagnostic exams consisted of an X-Ray and an MRI on an unspecified date. The results of these diagnostic exams were not included in the clinical notes. His surgical history was not indicated in the clinical notes. On 01/03/2014, the injured worker complained of right knee pain rated 3/10 and right hip pain rated 2/10. He reported that his right knee pain was intermittent and improved since his last injection. The physical exam revealed an unchanged clinical status and antalgic gait. His medications included Flur-Lido-A 240gm, Flurlido-A 30gm, Ultraflex-G 240gm, and Ultraflex-F 30gm. The treatment plan encompassed the continuation of acupuncture therapy and the use of Flur-Lido-A 240gm, Flurlido-A 30gm, Ultraflex-G 240gm, and Ultraflex-F 30gm. The rationale for the request was not clearly indicated in the clinical notes. The Request for Authorization for was signed and submitted on 01/03/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUNDED FLUR LIDO-A 240GM:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment, Chronic Pain Treatment Guidelines TOPICAL AGENTS Page(s): 111.

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

**Decision rationale:** The active ingredients in this compound include Flurbiprofen 20%, Lidocaine 5%, and Amitriptyline 5%. The MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. In regards to the use of topical NSAIDs, the guidelines state that this treatment may be recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment; however, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. In regards to lidocaine for the use of a topical analgesic, the guidelines recommend lidocaine for localized peripheral pain after there has been evidence of a trial of first line therapy. Topical lidocaine, in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine, whether creams, lotions or gels, are indicated for neuropathic pain other than Lidoderm. The clinical notes fail to indicate that the injured worker had a diagnosis of neuropathic pain or any or any objective findings that indicated neuropathic etiology to support the use of a topical analgesic. As the requested compound topical medication contains one or more ingredients that are not recommended, the compound is also not recommended. Additionally, the request as submitted did not specify a frequency of use or site of application. Therefore, the request is not medically necessary.

**FLURLIDO - A 30GM:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines LIDOCAINE Page(s): 112.

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

**Decision rationale:** The active ingredients in this compound include Flurbiprofen 20%, Lidocaine 5%, and Amitriptyline 5%. The MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. In regards to the use of topical NSAIDs, the guidelines state that this treatment may be recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment;

however, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. In regards to lidocaine for the use of a topical analgesic, the guidelines recommend lidocaine for localized peripheral pain after there has been evidence of a trial of first line therapy. Topical lidocaine, in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine, whether creams, lotions or gels, are indicated for neuropathic pain other than Lidoderm. The clinical notes fail to indicate that the injured worker had a diagnosis of neuropathic pain or any or any objective findings that indicated neuropathic etiology to support the use of a topical analgesic. As the requested compound topical medication contains one or more ingredients that are not recommended, the compound is also not recommended. Additionally, the request as submitted did not specify a frequency of use or site of application. Therefore, the request is not medically necessary.

**ULTRAFLEX - G 240GM:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MUSCLE RELAXANTS.

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

**Decision rationale:** The active ingredients in Ultraflex 240gm include Gabapentin 10%, Cyclobenzaprine 6% and Tramadol 10%. The MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. The guidelines do not recommended topical Gabapentin because there is no peer-reviewed literature to support its use as a topical analgesic. In regards to cyclobenzaprine, the guidelines state that the use of topical muscle relaxants is not recommended as there is no evidence for use of any muscle relaxant as a topical product. The clinical notes failed to indicate that the injured worker had a diagnosis of neuropathic pain or any objective findings that indicated neuropathic etiology to warrant the use of a topical analgesic. The use of Gabapentin and Cyclobenzaprine is not supported due to lack of clinical based evidence to support their use as topical products. As the requested compound topical medication contains one or more ingredients that are not recommended, the compound is also not recommended. Additionally, the request as submitted did not specify a frequency of use or site of application. Therefore, due to lack of documentation indicating neuropathic pain and the lack of support to use Gabapentin and Cyclobenzaprine in a topical form, the request is not supported. As such, the request is not medically necessary.

**ULTRAFELX - F 30GM:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MUSCLE RELAXANT.

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

**Decision rationale:** The active ingredients in Ultraflex 30gm include Gabapentin 10%, Cyclobenzaprine 6% and Tramadol 10%. The California MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend topical Gabapentin because there is no peer-reviewed literature to support its use as a topical analgesic. In regards to cyclobenzaprine, the guidelines state that the use of topical muscle relaxants is not recommended as there is no evidence for use of any muscle relaxant as a topical product. The clinical notes failed to indicate that the injured worker had a diagnosis of neuropathic pain or any objective findings that indicated neuropathic etiology to warrant the use of a topical analgesic. The use of Gabapentin and Cyclobenzaprine is not supported due to lack of clinical based evidence to support their use as topical products. As the requested compound topical medication contains one or more ingredients that are not recommended, the compound is also not recommended. Additionally, the request as submitted did not specify a frequency of use or site of application. Therefore, due to lack of documentation indicating neuropathic pain and the lack of support to use Gabapentin and Cyclobenzaprine in a topical form, the request is not supported. As such, the request is not medically necessary.