

Case Number:	CM15-0000348		
Date Assigned:	01/09/2015	Date of Injury:	09/05/2014
Decision Date:	03/05/2015	UR Denial Date:	12/04/2014
Priority:	Standard	Application Received:	01/02/2015

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: Family Practice

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 24-year-old male, with a reported date of injury of 09/05/2014. He has reported left abdomen, neck, and back pain. The diagnoses have included cervical spine sprain/strain, lumbar spine sprain/strain, muscle spasms, left inguinal pain, rule out hernia, and abdominal wall strain. Treatments to date have included six (6) physical therapy sessions, and a pelvic ultrasound on 10/22/2014, with no evidence of a hernia. Currently, the injured worker complains of intermittent upper back and low back pain, rated a 5 out of 10, with a tightening sensation and pinching; and constant left abdominal pain, rated an 8 out of 10, with burning and throbbing sensations. The injured worker is unable to run, and lift. He has difficulty with lifting more than five pounds and carrying grocery bags. The physical examination showed tenderness to palpation of the left inguinal canal, tenderness to palpation with spasms of the upper trapezius muscles bilaterally, tenderness to palpation with spasms of the lumbar paraspinals. On 12/04/2014, Utilization Review (UR) non-certified the request for cyclobenzaprine 2%/Flurbiprofen 25% 180grams #1 and Capsaicin 0.025%/Flurbiprofen 15%/Gabapentin 10%/Menthol 2%/Camphor 2% 180 grams #1. The UR physician noted that Cyclobenzaprine, Flurbiprofen, and Gabapentin are not recommended in topical format. The Guidelines indicate if one ingredient of a compound is not recommended, the entire compound is not recommended. The ACOEM Guidelines and Official Disability Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 2%, Flurbiprofen 25%, 180gm #1: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics as a treatment modality. These guidelines state the following: Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, alpha agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). 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. Fluribiprofen is a non-steroidal antiinflammatory agent (NSAID). 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Cyclobenzaprine is a muscle relaxant. The MTUS guidelines state the following regarding the use of topical muscle relaxants: "There is no evidence for use of any other muscle relaxant as a topical product." In this case, the compounded medication contains one drug, cyclobenzaprine, that is not recommended. As cited above, this finding makes the entire compound an unnecessary treatment. Therefore, Cyclobenzaprine and Flurbiprofen topical analgesic is not considered as medically necessary.

Capsaicin 0.025%, Flurbiprofen 15%, Gabapentin 10%, Menthol 2%, Camphor 2%, 180gm, #1: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics as a treatment modality. Relevant comments from these guidelines state the following: Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). 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. Flurbiprofen, a component of this topical analgesic is a non-steroidal anti-inflammatory agent (NSAID). MTUS comments regarding the use of topical NSAIDs are as follows: 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. The MTUS comments regarding capsaicin, another component of this topical analgesic are as follows: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The MTUS comments regarding gabapentin, another component of this topical analgesic are as follows: Gabapentin: Not recommended. There is no peer-reviewed literature to support use. In this case gabapentin is listed as a non-recommended agent for use in a topical analgesic. Given the above cited MTUS recommendations, the use of gabapentin makes this an unnecessary treatment. Further, it should be noted that the use of a topical NSAID in this case is not supported as well. Finally, the patient does not have osteoarthritis or a neuropathy for which capsaicin may be used. In summary, there is no medical justification to the use of topical Capsaicin, Flurbiprofen, Gabapentin, Menthol and Camphor.