

<b>Case Number:</b>	CM15-0024523		
<b>Date Assigned:</b>	02/17/2015	<b>Date of Injury:</b>	12/21/2000
<b>Decision Date:</b>	03/31/2015	<b>UR Denial Date:</b>	01/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/09/2015

### 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: Preventive Medicine, Occupational 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 67 year old female, who sustained an industrial injury on December 21, 2000. She has reported a right knee injury. The diagnoses have included bilateral knee derangement. Treatment to date has included steroid injections, x-rays, topical compounded pain medication, and pain medication, proton pump inhibitor, and sleeping medications. On December 29, 2014, the treating physician noted bilateral knee pain, left greater than right. The knees were swollen. Bilateral knee replacements were planned, with the right knee being done first. Current medications included oral pain and a topical compounded pain medication. The physical exam revealed tenderness to palpation of the posterior, medial, and lateral ligament lines of bilateral knees, positive effusion bilateral knees, and positive McMurray's sign bilaterally. On February 9, 2015, the injured worker submitted an application for IMR for review of requests for 1 prescription for Norco (Hydrocodone Bitartrate & Acetaminophen) 10/325mg #120, 1 prescription for Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.00375% topical cream 15gm, 1 prescription for Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.00375% topical cream 60gm, and 1 prescription for Fexmid 7.5mg #120. The Norco was non-certified based on the lack of documentation of improvement in function or pain with long-term opioid use. In addition, the Utilization Review on January 8, 15 determined the patient should be weaned from Norco due to lack of improvement and upcoming knee replacement. It appears the patient has not been taking the Norco per the urine drug screen from December 31, 2014, and he was recently supplied with a sufficient quantity for weaning support at this time. The Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.00375% topical

creams were non-certified based on the guidelines do not recommend compounded product that contains at least one drug that is not recommended. This compounded medication contains menthol and camphor that are not recommended for long-term topical use over 12 weeks. The patient had been using this medication since at least September 26, 2014. In addition, there was a lack of documentation of any type of improvement with the use of this topical compounded medication for at least 12 weeks, which is longer than the guidelines recommend utilization of topical non-steroidal anti-inflammatory drugs. The Fexmid was non-certified based on lack of evidence of the patient experiencing muscle spasms or being treated for chronic low back pain. The California Medical Treatment Utilization Schedule (MTUS), Chronic Pain Medical Treatment Guidelines was cited.

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

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

**1 Prescription of Norco (Hydrocodone Bitartrate & Acetaminophen) 10/325mg #120:  
Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-9, Chronic Pain Treatment Guidelines Opioids Page(s): 60-1, 74-96.

**Decision rationale:** Hydrocodone-Acetaminophen (Norco) is a mixed medication made up of the short acting, opioid, hydrocodone, and acetaminophen, better known as Tylenol. It is recommended for moderate to moderately severe pain with usual dosing of 5-10 mg hydrocodone per 325 mg of acetaminophen taken as 1-2 tablets every 4-6 hours. Maximum dose according to the MTUS is limited to 4 gm of acetaminophen per day, which is usually 120 mg/day of hydrocodone. According to the MTUS, opioid therapy for control of chronic pain, while not considered first line therapy, is considered a viable alternative when other modalities have been tried and failed. This is the crux of the decision for use of this medication. First-line medications for chronic pain, such as anti-depressants or anti-epileptic drugs, have not been tried. Additionally, the provider has not documented beneficial effects of decreased pain or increased function from use of this medication. Finally, the risk with chronic opioid therapy is the development of addiction, overdose and death. The pain guidelines in the MTUS directly address this issue and have outlined criteria for monitoring patients to prevent iatrogenic morbidity and mortality. Recent urine drug screening did not show that the patient is actually taking Norco although the test indicated that it was prescribed at the time of the test. Considering all the above, medical necessity for continued use of Norco has not been established.

**1 Prescription of Flurbiprofen 25%/Menthol 10%/ Camphor 3%/ Capsaicin 0.0375%  
Topical Cream 15gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin, NSAIDs Page(s): 28-9, 67-73, 111-13.

**Decision rationale:** Flurbiprofen 25%-Menthol 10%-Camphor 3%-Capsaicin 0.0375% Topical Cream is a combination product formulated for use as a topical analgesic. Topical analgesic medications have been shown to give local analgesia. The use of topical agents to control pain is considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use and their use is primarily recommended for osteoarthritis or neuropathic pain when trials of antidepressants and anticonvulsants have failed. Flurbiprofen is classified as non-steroidal anti-inflammatory drug (NSAID) and studies have shown NSAIDs have been effective when given topically in short-term use trails for chronic musculoskeletal pain. However, long-term use of topical NSAIDs has not been adequately studied. Menthol is a topical analgesic medication with local anesthetic and counter-irritant qualities. The MTUS does not recommend for or against its use for chronic pain. Camphor is a topical medication with local anesthetic and antimicrobial properties. The MTUS does not recommend for or against its use for chronic pain. Capsaicin is a capsaicinoid compound with analgesic properties usually formulated as 0.025% for osteoarthritis or 0.075% for neuropathic pain. It is used medically in the form of a topical ointment, spray or patch and is indicated for the temporary relief of minor aches and pains of muscles and joints. It has also been used to treat the itching and inflammation caused by psoriasis. When compared to a placebo, its use has been superior in relieving chronic neuropathic pain and musculoskeletal pain. However, there are no evidence-based studies using 0.0375% preparations and no evidence that this higher dose formulation is superior to 0.025%. The MTUS recommends its use as option for treating pain in patients intolerant to other treatments. It is important to note the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The MTUS recommends topical NSAIDs for short-term use only as there are no long-term studies of their effectiveness or safety. This patient has no documented intolerance to other treatments nor contraindications for use of other approved evidence-based chronic pain medications such as antidepressants, oral NSAIDs or antiepileptic medications. However, she has been using this medication for over a month and noticed increased pain when not able to get prescription refilled. Furthermore, she tolerates its use without significant side effects. In consideration of all the above, medical necessity for continued use of this medication has not been established.

**1 Prescription of Flurbiprofen 25%/Menthol 10%/ Camphor 3%/ Capsaicin 0.0375% Topical Cream 60gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin, NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 28-9, 67-.

**Decision rationale:** Flurbiprofen 25%-Menthol 10%-Camphor 3%-Capsaicin 0.0375% Topical Cream is a combination product formulated for use as a topical analgesic. Topical analgesic medications have been shown to give local analgesia. The use of topical agents to control pain is

considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use and their use is primarily recommended for osteoarthritis or neuropathic pain when trials of antidepressants and anticonvulsants have failed. Flurbiprofen is classified as non-steroidal anti-inflammatory drug (NSAID) and studies have shown NSAIDs have been effective when given topically in short-term use trials for chronic musculoskeletal pain. However, long-term use of topical NSAIDs has not been adequately studied. Menthol is a topical analgesic medication with local anesthetic and counter-irritant qualities. The MTUS does not recommend for or against its use for chronic pain. Camphor is a topical medication with local anesthetic and antimicrobial properties. The MTUS does not recommend for or against its use for chronic pain. Capsaicin is a capsaicinoid compound with analgesic properties usually formulated as 0.025% for osteoarthritis or 0.075% for neuropathic pain. It is used medically in the form of a topical ointment, spray or patch and is indicated for the temporary relief of minor aches and pains of muscles and joints. It has also been used to treat the itching and inflammation caused by psoriasis. When compared to a placebo, its use has been superior in relieving chronic neuropathic pain and musculoskeletal pain. However, there are no evidence-based studies using 0.0375% preparations and no evidence that this higher dose formulation is superior to 0.025%. The MTUS recommends its use as option for treating pain in patients intolerant to other treatments. It is important to note the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The MTUS recommends topical NSAIDs for short-term use only as there are no long-term studies of their effectiveness or safety. This patient has no documented intolerance to other treatments nor contraindications for use of other approved evidence-based chronic pain medications such as antidepressants, oral NSAIDs or antiepileptic medications. However, she has been using this medication for over a month and noticed increased pain when not able to get prescription refilled. Furthermore, she tolerates its use without significant side effects. In consideration of all the above, medical necessity for continued use of this medication has not been established.

### **1 Prescription of Fexmid 7.5mg #120: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Muscle Relaxants, Cyclobenzaprine Page(s): 41-2, 63-66.

**Decision rationale:** Cyclobenzaprine (Fexmid) is classified as a sedating skeletal muscle relaxant. It is recommended to be used three times per day. This class of medications can be helpful in reducing pain and muscle tension thus increasing patient mobility. Muscle relaxants as a group, however, are recommended for short-term use only as their efficacy appears to diminish over time. In fact, studies have shown cyclobenzaprine's greatest effect is in the first 4 days of treatment after which use may actually hinder return to functional activities. Muscle relaxants are considered no more effective at pain control than non-steroidal anti-inflammatory medication (NSAIDs) and there is no study that shows combination therapy of NSAIDs with muscle relaxants has a demonstrable benefit. This patient has been on muscle relaxant therapy for over 2 months. There are no present symptoms of muscle spasms or indications that these

medications have improved patient's mobility or ability to return to work. Medical necessity for continued use of muscle relaxants (as a class) or Fexmid (specifically) has not been established.