

Case Number:	CM15-0025071		
Date Assigned:	02/17/2015	Date of Injury:	07/15/2012
Decision Date:	04/03/2015	UR Denial Date:	01/13/2015
Priority:	Standard	Application Received:	02/10/2015

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, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 45 year old male, who sustained an industrial injury on July 15, 2012. The diagnoses have included cervical spine sprain/strain, left shoulder contusion with rotator cuff tendinopathy, lumbar spine sprain/strain, left knee sprain/strain, left knee internal derangement, significant left shoulder impingement, and lateral tibial plateau non-displaced fracture per x-ray. Treatment to date has included home exercise program, pain and non-steroidal anti-inflammatory medications, topical compounded cream, and work modifications. On December 19, 2014, the treating physician noted persistent left shoulder pain with limited range of motion. The pain was rated 5/10. The injured worker used pain medication as needed. The physical exam revealed a slightly antalgic gait. The left shoulder had mild tenderness of the acromioclavicular joint and lateral deltoid. There were positive Hawkin's, Neer's, and nerve impingement signs. There was full range of motion w. end range pain, and pain with resisted forward flexion and abduction. Motor strength was moderately decreased. The left knee had infrapatellar tenderness with prepatellar sensitivity, no crepitus, positive pain on partial deep knee bend, no laxity or effusion, trace positive Murray's maneuver and Pivot Shift, and negative anterior and posterior signs. On February 10, 2015, the injured worker submitted an application for IMR for review of requests for 1 prescription for Flurbiprofen/Baclofen/ Cyclobenzaprine 20/2/2% cream- apply 1-2 grams to affected area BID-TID (twice a day to three times a day) as a topical anti-inflammatory #120 and Ketoprofen/Gabapentin/Diclofenac/ Lidocaine 15/8/5/5% cream- apply 1-2 grams to affected area BID-TID (twice a day to three times a day) for neuropathic pain #120. The Flurbiprofen/Baclofen/ Cyclobenzaprine cream was non-certified

based on any compounded product that contains at least one drug that is not recommended the entire compounded cream is not recommended. Baclofen is not recommended as a topical muscle relaxant, and there is a lack of evidence for use of any other muscle relaxant as a topical product. In addition, there was a lack of evidence that the patient has failed oral non-steroidal anti-inflammatory drugs, Baclofen or Cyclobenzaprine to support topical use. The Ketoprofen/Gabapentin/Diclofenac/ Lidocaine cream was non-certified based on any compounded product that contains at least one drug that is not recommended the entire compounded cream is not recommended. Ketoprofen and Gabapentin are not recommended by the guidelines for topical use. In addition, there was a lack of evidence that the patient has failed non-steroidal anti-inflammatory drugs, oral gabapentin or Lyrica to support topical analgesics at this time. The California Medical Treatment Utilization Schedule (MTUS), Chronic Pain Medical Treatment Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Baclofen/Cyclobarizaprine 20/2/2% cream apply 1-2grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-113.

Decision rationale: Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) 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." Flurbiprofen may be indicated for the injured worker's knee pain. Per MTUS p113 with regard to topical baclofen, "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." Baclofen and cyclobenzaprine are not indicated. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications 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. (Namaka, 2004) 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. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. Regarding the use of multiple medications, MTUS p60 states Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually. Because topical baclofen and cyclobenzaprine is not indicated, the compound is not recommended. This request is not medically necessary.

Ketoprofen/Gabapentin/Diclofenac/Lidocaine 15/8/5/5%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-113.

Decision rationale: Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." With regard to topical Ketoprofen, the MTUS CPMTG states "This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006)". Regarding topical lidocaine, MTUS states (p112) "Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995). " Per MTUS with regard to topical NSAIDs (p112), "(Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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." The documentation contains no evidence of osteoarthritis or tendinitis. Diclofenac is not indicated. Regarding the use of multiple medications, MTUS p60 states Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually. Note the statement on page 111: Any compounded product that contains

at least one drug (or drug class) that is not recommended is not recommended. As several of the agents in this compound are not recommended, the request is not medically necessary.