

Case Number:	CM15-0019972		
Date Assigned:	02/09/2015	Date of Injury:	05/25/2012
Decision Date:	04/03/2015	UR Denial Date:	12/29/2014
Priority:	Standard	Application Received:	02/02/2015

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, 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 47 year old male, who sustained an industrial injury on May 25, 2012. He has reported a back injury. The diagnoses have included lumbosacral neuritis or radiculitis. Treatment to date has included medications, and physical therapy. Currently, the IW complains of low back pain. He reports his pain to be 5-6/10 on a pain scale. Physical findings are indicated to be a decreased range of motion to the lumbar spine, and tenderness to both sacroiliac joints and the lumbar spine region. He has a positive straight leg raise test for both legs. On December 29, 2014, Utilization Review non-certified one container of compounded: Flubiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 2%, Camphor 2%, and Capsaicin 0.025% in cream base, 210 grams, and one container of: Gabapentin 10%, Amitriptyline 10%, and Bupivacaine 5% in cream, 210 grams, based on MTUS, Chronic Pain Medical Treatment guidelines. On January 22, 2013, the injured worker submitted an application for IMR for review of one container of compounded: Flubiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 2%, Camphor 2%, and Capsaicin 0.025% in cream base, 210 grams, and one container of: Gabapentin 10%, Amitriptyline 10%, and Bupivacaine 5% in cream, 210 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 container of compounded Flurbiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 2%, Camphor 2% and Capsaicin 0.025 in cream base 210 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112.

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), "(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. Flurbiprofen is not indicated. 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 is not indicated. Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "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 CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of dexamethasone, menthol or camphor. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since several components are not medically indicated, then the overall product is not indicated per MTUS as outlined below. 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. The request is not medically necessary.

1 container of Gabapentin 10%, Amitriptyline 10%, and Bupivacaine 5% in cream 210 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112.

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." Per the article "Topical Analgesics in the

Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ($P < .05$) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of bupivacaine. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since bupivacaine and gabapentin are not medically indicated, then the overall product is not indicated per MTUS as outlined below. 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. 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.