

<b>Case Number:</b>	CM14-0020268		
<b>Date Assigned:</b>	04/25/2014	<b>Date of Injury:</b>	02/25/2003
<b>Decision Date:</b>	07/25/2014	<b>UR Denial Date:</b>	02/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/18/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a Physician Reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The Physician Reviewer is Board Certified in Internal Medicine, and is licensed to practice in Virginia and the District of Columbia. 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 Physician 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:

This is a patient who sustained injury on Feb 25 2003. [REDACTED] saw the patient on Oct 23, and Nov 20, 2013 for bilateral hand pain, lower back pain, and bilateral hip pain. He prescribed the following: soma, norco, gabapentin 800mg po qhs. [REDACTED] saw the patient on Dec 18, 2013 for the same pain complaints as noted on prior visits. He prescribed the following: soma, norco, gabapentin 800mg po qhs. This review is to evaluate ketamine, gabapentin and flurbiprofen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gabapentin 100% (Drug Strength):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17.

**Decision rationale:** Gabapentin is recommended for neuropathic pain (pain due to nerve damage). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been

directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the trigger for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs (anti-epilepsy drugs) depends on improved outcomes versus tolerability of adverse effects. AEDs are associated with teratogenicity, so they must be used with caution in woman of childbearing age. Preconception counseling is recommended for anticonvulsants (due to reductions in the efficacy of birth control pills). According to the MTUS guidelines, topical analgesia is not recommended for patients with neuropathic pain when trials of antidepressants and anticonvulsants have failed. Therefore it is not medically indicated.

**Ketamine Hydrochloride 100% (Drug Strength): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56.

**Decision rationale:** There are no quality studies that support the use of ketamine for chronic pain, but it is under study for CRPS (chronic regional pain syndrome). Ketamine is an anesthetic in animals and humans, and also a drug of abuse in humans, but ketamine may offer a promising therapeutic option in the treatment of appropriately selected patients with intractable CRPS. More study is needed to further establish the safety and efficacy of this drug. One very small study concluded that ketamine showed a significant analgesic effect on peripheral neuropathic pain, but the clinical usefulness is limited by disturbing side effects. Another study by the same author with a sample size too small for the ODG (10), concluded that ketamine showed a significant analgesic effect in patients with neuropathic pain after spinal cord injury, but ketamine was associated with frequent side effects. According to the MTUS guidelines, Ketamine is not recommended for pain treatment and is therefore not medically necessary.

**Flurbiprofen:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics Page(s): 111-112.

**Decision rationale:** According to the MTUS, Osteoarthritis (including knee and hip): NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate

pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function.

**Back Pain - Acute exacerbations of chronic pain:** NSAIDs are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician.

**Back Pain -Chronic low back pain:** NSAIDs are recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. For neuropathic pain: there is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain.

Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage.

**Non-steroidal antiinflammatory agents (NSAIDs):** 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.

**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.

**Neuropathic pain:** Not recommended as there is no evidence to support use.

**FDA-approved agents:**

**Voltaren Gel 1% (diclofenac):** Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus.

**Non FDA-approved agents:**

**Ketoprofen:** This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Absorption of the drug depends on the

base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. According to the MTUS, topical analgesia is not recommended for patients with neuropathic pain when trials of antidepressants and anticonvulsants have failed. Therefore it is not medically indicated.