

<b>Case Number:</b>	CM13-0026193		
<b>Date Assigned:</b>	11/22/2013	<b>Date of Injury:</b>	04/10/2012
<b>Decision Date:</b>	01/21/2014	<b>UR Denial Date:</b>	08/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/18/2013

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in California and Texas. 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 patient is a 54-year-old female who reported an injury on 03/02/2011. The documentation submitted for review indicates that the patient was evaluated on 09/05/2013 with continued complaints of the bilateral shoulders, cervical spine, and lumbar spine. The notes indicate that the patient has limited range of motion in the cervical and lumbar spine as well as in the right and left shoulders. Medication management consists of Tylenol No. 4, Voltaren gel, and cyclobenzaprine 7.5 mg. This patient is currently assessed with shoulder impingement bilaterally as well as cervical, thoracic, and lumbar spine sprain/strain. The current request for consideration is for Diclofenac topical cream, Acetaminophen/Codeine, and Zolpidem.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Diclofenac Topical Cream/gel 100gm:** 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 California MTUS states Voltaren® Gel 1% (diclofenac) is an FDA-approved agent indicated for relief of osteoarthritis pain in joints that lends themselves to topical

treatment such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip or shoulder. The 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 California MTUS states Non-steroidal antiinflammatory agents have limited demonstrated efficacy in clinical trials and have been inconsistent with most studies being small and of short duration. They have been found in studies 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. However, again 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. The California MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are 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; however, 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, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. While the referenced Guidelines support the recommendation for the use of Voltaren gel in a topical formulation, there is no clearly demonstrated efficacy indicated in the notes submitted for review to support the recommendation for continued use of Voltaren gel. Given the above, the request for Diclofenac Topical Cream/gel 100gm is not medically necessary and appropriate.

**Zolpidem:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Ambien.

**Decision rationale:** The California MTUS/ACOEM Guidelines do not specifically address Zolpidem. However, the Official Disability Guidelines state that Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. The documentation submitted for review indicates that an evaluation of the patient was completed on 07/16/2013 with respect to the patient's prescribed medications. The notes indicated that at that time the patient was prescribed zolpidem and that the patient had complaints of morning grogginess with the use of Ambien, which limited her activities of daily living. Moreover, recommendation of the referenced Guidelines is only for a

short 2 to 6 week treatment for insomnia with zolpidem. Therefore, the request for Zolpidem is not medically necessary and appropriate.