

<b>Case Number:</b>	CM14-0036144		
<b>Date Assigned:</b>	06/23/2014	<b>Date of Injury:</b>	04/28/2001
<b>Decision Date:</b>	08/08/2014	<b>UR Denial Date:</b>	02/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/24/2014

### 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. The expert reviewer is Board Certified in Internal Medicine & Emergency Medicine and is licensed to practice in Florida. 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/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 58 year-old with a date of injury of 04/28/01. A progress report associated with the request for services, dated 01/28/14, identified subjective complaints of bilateral shoulder pain. Objective findings included tenderness to palpation with decreased range-of-motion of the shoulders bilaterally. Diagnoses included bilateral adhesive capsulitis and partial-thickness supraspinatus tears bilaterally. Treatment has included bilateral arthroscopy and oral and topical analgesics. A Utilization Review determination was rendered on 02/25/14 recommending non-certification of Amitramadol-DM transderm 240 gm and Gabapentin 6%/Ketoprofen 20%/Lidocaine HCL 6.15% transderm 240 gm cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Amitramadol-DM transderm 240 gm:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics Other Medical Treatment Guideline or Medical Evidence: Clin J Pain. 2008 Jan;24(1):51-5; www.updates.pain-topics.org; J Anesth. 2010 Oct;24(5):705-8.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Neither the MTUS nor the Official Disability Guidelines (ODG) specifically addresses the use of amitriptyline as a topical agent. A randomized, placebo-controlled crossover study examined topical 5% amitriptyline with 5% lidocaine topical in patients with neuropathic pain. The study found that topical amitriptyline was not effective. Tramadol is an opioid analgesic being used as a topical agent. The efficacy of topical tramadol is not specifically addressed in the MTUS or the Official Disability Guidelines (ODG). There is some data that topical tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. The Guidelines state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Likewise, in this case, there is no documentation of the failure of conventional therapy or documented functional improvement for amitriptyline or tramadol topical. Therefore, the record does not document the medical necessity for topical Amitramadol.

**Gabapentin 6%/Ketoprofen 20%/Lidocaine HCL 6.15% transderm 240 gm cream:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen 20% is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and or short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is diclofenac. Ketoprofen is not approved and it has an extremely high incidence of photocontact dermatitis and photosensitization reactions. Gabapentin is an anti-epilepsy drug. The MTUS Guidelines state that gabapentin is: Not recommended. There is no peer-reviewed literature to

support use. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, there is no documented medical necessity for the addition of gabapentin in the topical formulation for this patient. Lidocaine is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore there is no medical necessity for the compounded formulation.