

<b>Case Number:</b>	CM13-0024039		
<b>Date Assigned:</b>	10/11/2013	<b>Date of Injury:</b>	03/05/2012
<b>Decision Date:</b>	01/24/2014	<b>UR Denial Date:</b>	08/28/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/13/2013

### 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 Physical Medicine and Rehabilitation, and is licensed to practice in California. 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:

The injured worker is a 43 year old female who had a date of injury of March 5, 2012. The diagnosis includes low back pain, cervical spine pain, thoracic spine pain, shoulder rotator cuff tear, chair with high intensity zone. According to a recent primary treating physician's progress report dated September 24, 2013, the patient rates the severity of her cervical pain rated 3-4 on a scale of 1 to 10 with 10 being the worst. The patient indicates muscle relaxants worsen the condition as well as looking and looking down. The patient continues to have low back pain which is rated a two out of a scale of 1 to 10. Her current medications include Motrin, Norco, and Lidoderm. Physical examination of the musculoskeletal system reveals that Dayton station examination reveals mid position without abnormalities. Inspection and palpation of bones, joints and muscles is unremarkable. Neurologic examination is unremarkable. Neck examination reveals pain to palpation over the bilateral C3-4, C4-5, and C5-6 facet capsules. Lumbosacral examination reveals positive Gaenslen's maneuver bilaterally, positive Patrick's maneuver bilaterally, and straight leg raise is positive bilaterally at 45°. Utilization review in a report dated August 28, 2013 noncertified the Lidoderm patch. The rationale for this is the lack of documentation of medical necessity including "failed trials of anticonvulsants and antidepressants, as well as the claimant being unresponsive and intolerant to all other treatments." In the recommendation section, the utilization reviewer specified that in order for this medication to be considered for certification on subsequent review, "evidence of measurable subjective and or functional benefit as a result of the medication, documentation of medical necessity including failed trials of anticonvulsants and antidepressants, as well as the claimant being unresponsive and intolerant to all other treatments will be required."

### IMR ISSUES, DECISIONS AND RATIONALES

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

**The request for Lidoderm Patch:** Upheld

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

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

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify the following regarding topical Analgesics: "Recommended as an option as indicated below. 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,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\beta$  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. 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. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic<sup>®</sup> (fentanyl transdermal system).]" The Chronic Pain Medical Treatment Medical Guidelines on pages 112-113 specify the following regarding topical Lidocaine: "Indication: 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). Topical lidocaine, in the formulation of a dermal patch (Lidoderm<sup>®</sup>) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved p