

<b>Case Number:</b>	CM15-0101372		
<b>Date Assigned:</b>	06/03/2015	<b>Date of Injury:</b>	11/05/2004
<b>Decision Date:</b>	07/02/2015	<b>UR Denial Date:</b>	05/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/27/2015

### 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: North Carolina  
 Certification(s)/Specialty: Family Practice

### 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 67 year old female sustained an industrial injury to the back and hip on 11/5/04. Previous treatment included magnetic resonance imaging, trochanteric bursa injections, home exercise and medications. In a PR-2 dated 8/5/14, the injured worker reported complained of ongoing low back pain with radiation into bilateral hips and lower extremities, rated 3-4/10 on the visual analog scale. The pain could increase to 8/10 with prolonged sitting, standing and ambulation. The injured worker reported that Lidoderm patches and topical compound cream were effective in managing her low back pain. Physical exam was remarkable for lumbar spine with mild tenderness to palpation to the paraspinal musculature, moderate tenderness to palpation to the bilateral trochanteric processes, limited range of motion in all planes and normal lower extremity strength. Current medications included Cymbalta, Norco, Lidoderm patch and topical compound cream. Current diagnoses included chronic low back pain, lumbar spine degenerative disc disease, lumbar spine radiculopathy and bilateral trochanteric bursitis. The treatment plan included refilling Cymbalta, Lidoderm patches and compound cream, continuing home exercise and follow up for a better fitting back brace.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 topical compound cream (Ketoprofen 15%, Cyclobenzaprine 2%, Gabapentin 10% and Lidocaine 2%) 240 grams: 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 chronic pain medical treatment guidelines section on topical analgesics states: 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, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, 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 requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore the request is not medically necessary.

**60 patches of Lidoderm 5%: 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 lidocaine Page(s): 111-112.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical lidocaine states: 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) 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 products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic

muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) This medication is recommended for localized peripheral pain. The patient has no documented failure of all first line agents indicated for the treatment of neuropathic pain as outlined above. Therefore criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.