

<b>Case Number:</b>	CM15-0136196		
<b>Date Assigned:</b>	07/24/2015	<b>Date of Injury:</b>	11/08/2014
<b>Decision Date:</b>	08/31/2015	<b>UR Denial Date:</b>	06/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/14/2015

### 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 (IW) is a 55-year-old female who sustained an industrial injury on 11/08/2014. Diagnoses/impressions include cervicgia, lumbago, lumbar disc protrusion, lumbar radiculitis and left ankle injury. Treatment to date has included medications and physical therapy (PT). According to the progress notes dated 5/6/15, the IW reported constant, severe neck pain, rated 8/10, radiating to the lumbar spine and relieved by medications; frequent, severe low back pain, rated 8/10, radiating to the cervical spine and relieved by PT and rest; and constant, moderate burning left ankle pain, numbness and cramping, rated 7/10, relieved by medication. On examination, ranges of motion (ROM) of the cervical spine were decreased and painful with flexion 35 degrees, extension 45 degrees, lateral bending 30 degrees, bilaterally, and rotation 70 degrees, bilaterally. ROM of the lumbar spine was also painful. Flexion was 35 degrees, extension and bilateral lateral bending was 10 degrees. The L5-S1 spinous processes were tender to palpation and straight leg raise caused pain bilaterally. The left ankle ROM was 30 degrees flexion, 15 degrees extension, 20 degrees inversion and 10 degrees eversion; all ranges were painful. A request was made for Lidoderm 5% patch apply 1 patch to affected area every 12 hours, #120; Tramadol ER 100mg 1 tab daily, #45; Gabapentin 10%/Amitriptyline 10%/Bupivacaine 5%/Flurbiprofen 20%/Baclofen 5%/Dexamethasone 2%/Capsaicin 0.25%, 30 day supply 180 grams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol ER 100mg 1 tab PO QD #45: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76.

**Decision rationale:** Per MTUS Chronic Pain Medical Treatment Guidelines p76 regarding therapeutic trial of opioids, questions to ask prior to starting therapy include "(a) Are there reasonable alternatives to treatment, and have these been tried; (b) Is the patient likely to improve; (c) Is there likelihood of abuse or an adverse outcome." Progress report dated 6/24/15 notes that the patient complained of constant severe to 8/10 sharp, throbbing, burning neck pain radiating to lumbar spine. He also complained of frequent severe to 8/10 sharp, burning low back pain. The medical records contained UDS dated 3/31/15 was negative for Tramadol. This appears to be a new trial of opiate therapy, which is indicated. I respectfully disagree with the UR physician's denial based upon ongoing opiate therapy guidelines. The request is medically necessary.

**Lidoderm 5 percent patch apply 1 patch to affected area q 12 hours #120: Upheld**

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

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

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines p112 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." The medical records submitted for review do not indicate that there has been a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED). There is also no diagnosis of diabetic neuropathy or post-herpetic neuralgia. As such, Lidoderm is not recommended at this time. The request is not medically necessary.

**Gabapentin 10 percent/Amitriptyline 10 percent/Bupivacaine 5 percent/Flubiprofen 20 percent/Baclofen 5 percent/Dexamethasone 2 percent/Capsaicin 0.25 percent 30 day Supply 180 grams: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-112.

**Decision rationale:** Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS is silent on the use of topical Bupivacaine, however, topical lidocaine is only recommended for neuropathic 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). There is no documentation that the injured worker has failed trial of these first-line therapies. Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) 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." Flurbiprofen may be indicated. Per MTUS CPMTG p113, "There is no evidence for use of any other muscle relaxant as a topical product. [Besides Baclofen, which is also not recommended]" Baclofen is not indicated. Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Per the article "Topical Analgesics in the Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical Amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ( $P < .05$ ) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of dexamethasone. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since this component is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states, "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared

with the others." Therefore, it would be optimal to trial each medication individually. As multiple components are not recommended, the compound is not recommended. The request is not medically necessary.