

<b>Case Number:</b>	CM15-0122316		
<b>Date Assigned:</b>	07/06/2015	<b>Date of Injury:</b>	11/17/2000
<b>Decision Date:</b>	07/31/2015	<b>UR Denial Date:</b>	06/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/24/2015

### 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:

The injured worker (IW) is an 82-year-old female who sustained an industrial injury on 11/17/2000. Diagnoses include lumbar radiculopathy; lumbar spinal stenosis; lumbar facet arthropathy; status post lumbar spine surgery syndrome; and low back pain. Treatment to date has included medications, spinal surgery, physical therapy and chiropractic treatment. According to the progress notes dated 3/20/15, the IW reported chronic low back pain rated 8/10. She was post-op 1/6/15 posterior spinal fusion and revision laminectomy at L2-3 and hardware removal at L3-4. She also reported 50% pain relief with Exalgo and Dilaudid and Lidoderm patches to her low back area. With medications she was able to provide for her personal activities of daily living. She indicated she wanted to continue taking Norco past her 90-day post-operative period, even if she had to ask her primary care physician to prescribe it. The provider informed her that receiving prescriptions from another provider would violate the clinic's opioid agreement and her medications would stop. For her pain, the provider maintained her Exalgo, Hydromorphone, gabapentin and Lidoderm patches. On examination, the incision from her spinal surgery two months prior was well healed. There was no tenderness to the lower back, just some achiness. Her gait was mildly antalgic, she stooped forward, and a cane was used for walking. A request was made for Lidoderm DIS 5%, #60 with 3 refills and Neurontin tab 600mg, #120 with 3 refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lidoderm DIS 5% #60 Refills: 3:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm Page(s): 56-57.

**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. There is no documentation of failure of first line neuropathic pain medications. The patient has low back pain not localized peripheral pain. Therefore criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.

**Neurontin #600 #120 Refill: 3:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs Page(s): 16-22.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines gabapentin Page(s): 18.

**Decision rationale:** The California chronic pain medical treatment guidelines section on Neurontin states: Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin

monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen 2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. The requested medication is a first line agent to treatment neuropathic pain. The patient does have a diagnosis of neuropathic pain in the form of lumbar radiculopathy. Therefore the request is medically necessary.