

<b>Case Number:</b>	CM15-0192873		
<b>Date Assigned:</b>	10/06/2015	<b>Date of Injury:</b>	09/11/2007
<b>Decision Date:</b>	11/18/2015	<b>UR Denial Date:</b>	09/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/01/2015

### 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

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 is a 54-year-old female with a date of injury of September 11, 2007. A review of the medical records indicates that the injured worker is undergoing treatment for chronic lower back pain with left leg pain, multilevel lumbar left sided disc lesions, and myofascial pain and spasm. Medical records dated July 1, 2015 indicate that the injured worker complained of lower back pain rated, and leg pain that was better since the last injection, and pain rated at a level of 6 out of 10 on average. A progress note dated August 26, 2015 documented that there were no significant changes in the injured worker's lower back pain. Per the treating physician (August 26, 2015), the employee has returned to work. The physical exam dated July 1, 2015 reveals no new leg pain, symptoms of ongoing axial lower back pain on the left, and no new deficits. The progress note dated August 26, 2015 documented a physical examination that showed no changes since the examination performed on July 1, 2015. Treatment has included a transforaminal epidural steroid injection at L3-4 and L4-5 (April 15, 2015) and medications (Baclofen 10mg one to two tablets twice a day as needed and Fentanyl patches 50mcg per hour every forty eight hours since at least July of 2015; Celebrex 200mg twice a day as needed, Lyrica 75mg twice a day, Norco 10-325mg four times a day as needed, and Phentermine 37.5mg twice a day as needed since at least March of 2015). The treating physician documented that the urine drug screen dated May 6, 2015 showed consistent results. The original utilization review (September 10, 2015) non-certified a request for TNI cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TN1 cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The 54 year old patient complains of lower back pain and leg pain, rated at 6/10, along with poor quality of sleep, as per progress report dated 08/26/15. The request is for TN1 CREAM. The RFA for this case is dated 08/28/15, and the patient's date of injury is 09/11/07. Diagnoses, as per progress report dated 08/26/15, included chronic low back pain with left leg pain, Mx level left-sided disc lesions at L3, 4, 5, myofascial pain/spasm, thoracic and lumbosacral neuritis/radiculitis, pain in thoracic spine, lumbago and hypertension. The patient is status post laminectomy and decompression of L4-5 and L5-S1. Medications included Baclofen, Celebrex, Fentanyl patch, Lyrica, Norco, Phentermine, and Prilosec. The patient is working, as per the same progress report. The MTUS chronic pain guidelines, page 111-112 and Topical Analgesics section, do not support the use of topical NSAIDs such as Ketoprofen for axial, spinal pain, but supports its use for peripheral joint arthritis and tendinitis. The MTUS has the following regarding topical creams with Lidocaine: 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. MTUS Guidelines also provide clear discussion regarding topical compounded creams on pg 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, TN1 cream is first noted in progress report dated 05/06/15. It is not clear when the topical formulation was initiated. In progress report dated 08/26/15, the treater recommends the patient to continue TN1 cream to back/wrist. TN1 contains Ketoprofen and Lidocaine. MTUS does not recommend the use of topical Ketoprofen for axial, spinal pain. Additionally, MTUS guidelines do not support any other formulation of Lidocaine other than the topical patch. The guidelines also state that Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Hence, this request IS NOT medically necessary.