

<b>Case Number:</b>	CM15-0118782		
<b>Date Assigned:</b>	06/29/2015	<b>Date of Injury:</b>	10/28/2013
<b>Decision Date:</b>	07/28/2015	<b>UR Denial Date:</b>	06/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2015

### 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: Preventive Medicine, Occupational Medicine

### 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 49-year-old male who sustained an industrial injury on October 28, 2013. He has reported bilateral shoulder pain and has been diagnosed with status post right shoulder surgery, myofascial pain, and frozen shoulder. Treatment has included a home exercise program, heat, physical therapy, and medications. There was tenderness to palpation of the right shoulder with decreased range of motion. The treatment request included eszopiclone, Lidopro ointment, and TENS electrodes x 2 pairs.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retro: TENS electrodes x2 pairs with date of service 5/20/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 114-116.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy Section Page(s): 114-116.

**Decision rationale:** The use of TENS for chronic pain is not recommended by the MTUS Guidelines as a primary treatment modality, but a one-month home-based TENS trial may be considered if used as an adjunct to a program of evidence-based functional restoration in certain conditions. A home based treatment trial of one month may be appropriate for neuropathic pain and CRPS II and for CRPS I. There is some evidence for use with neuropathic pain, including diabetic neuropathy and post-herpetic neuralgia. There is some evidence to support use with phantom limb pain. TENS may be a supplement to medical treatment in the management of spasticity in spinal cord injury. It may be useful in treating MS patients with pain and muscle spasm. The criteria for use of TENS include chronic intractable pain (for one of the conditions noted above) with documentation of pain of at least three months duration, evidence that other appropriate pain modalities have been tried (including medication) and failed, a one month trial period of the TENS unit should be documented as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used as well as outcomes in terms of pain relief and function, and a treatment plan including specific short and long term goals of treatment. In this case, the injured worker has previously used a TENS unit for the shoulder but there is no documentation of the efficacy of the treatment to include pain relief or increase in function. The request for Retro: TENS electrodes x2 pairs with date of service 5/20/15 is not medically necessary.

**Retro: Eszopiclone 1mg (CIV) tablet with date of service 5/20/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (updated 04/30/15) - Online Version.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Insomnia Treatment Section.

**Decision rationale:** The MTUS Guidelines do not address pharmacologic sleep aids. Per the Official Disability Guidelines, pharmacological agents should only be used for insomnia management after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically whereas secondary insomnia may be treated with pharmacological and/or psychological measures. Eszopiclone (Lunesta) has demonstrated reduced sleep latency and sleep maintenance. It is the only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. Side effects: dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. In this case there is no evidence that the prescribed medication is helping the injured worker in terms of sleep hygiene or increase in function, therefore, the request for Eszopiclone 1mg (CIV) tablet with date of service 5/20/15 is not medically necessary.

**Retro: Lidopro ointment with date of service 5/20/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113, 105.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 28, 29, 111-113.

**Decision rationale:** Lidopro ointment contains the active ingredients methyl salicylate 27.5%, capsaicin 0.0375%, lidocaine 4.5% and menthol 10%. Salicylate topical is recommended by the MTUS Guidelines, as it is significantly better than placebo in chronic pain. The MTUS Guidelines recommend the use of topical capsaicin only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current evidence that this increase over a 0.025% formulation would provide any further efficacy. Topical lidocaine is used primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Menthol is not addressed by the MTUS Guidelines, but it is often included in formulations of anesthetic agents. It induces tingling and cooling sensations when applied topically. Menthol induces analgesia through calcium channel-blocking actions, as well as binding to kappa-opioid receptors. Menthol is also an effective topical permeation enhancer for water-soluble drugs. There are reports of negative effects from high doses of menthol such as 40% preparations. The use of topical analgesics are recommended by the MTUS Guidelines as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. In regards to Lidopro cream, the use of capsaicin at 0.0375% and topical lidocaine not in a dermal patch formulation are not recommended by the MTUS Guidelines, therefore, the request for retro: lidopro ointment with date of service 5/20/15 is not medically necessary.