

<b>Case Number:</b>	CM14-0187566		
<b>Date Assigned:</b>	11/17/2014	<b>Date of Injury:</b>	10/15/2011
<b>Decision Date:</b>	01/06/2015	<b>UR Denial Date:</b>	10/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/10/2014

### 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. The expert reviewer is Board Certified in Emergency Medicine and is licensed to practice in New York. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 54-year-old female who was injured on October 15, 2011. The patient continued to experience pain in her right shoulder and low back. Physical examination was notable for tenderness to palpation to the right shoulder and neck. Diagnoses included shoulder injury, cervical radiculopathy, and cervical degenerative disc disease. Treatment included medications, physical therapy, TENS unit, home exercise program, and chiropractic therapy. Requests for authorization for Terocin cream 120 ml and TENS patch #4 were submitted for consideration.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin cream ( methylsalic/capsaicin/menthol/lidocaine 25%/ 10%/ 2.5%/ 120 ml) dispensed on 9/27/2014:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 28, 105, 111-112. Decision based on Non-MTUS Citation Treatment Guidelines from the Medical Letter, April 1, 2013, Issue 128: Drugs for Pain Interventions and Guidelines

**Decision rationale:** Terocin is a topical multidrug compound, which contains methylsalicylate, Lidocaine, capsaicin, and menthol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Methylsalicylate is a topical salicylate and is recommended, being significantly better than placebo in chronic pain. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or cannot tolerate other treatments. It is recommended for osteoarthritis, fibromyalgia, and chronic non-specific back pain and is considered experimental in high doses. Topical analgesics containing menthol, methylsalicylate or capsaicin are generally well-tolerated, but there have been rare reports of severe skin burns requiring treatment or hospitalization. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.

**TENS patch x 4 , dispensed on 9/27/2014:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 114-115.

**Decision rationale:** TENS units are not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, including reductions in medication use, for neuropathic pain, phantom limb pain, spasticity, and multiple sclerosis. Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. Functional restoration programs (FRPs) are designed to use a medically directed, interdisciplinary pain management approach geared specifically to patients with chronic disabling occupational musculoskeletal disorders. These programs emphasize the importance of function over the elimination of pain. FRPs incorporate components of exercise progression with disability management and psychosocial intervention. Criteria for use of TENS are as follows: Chronic intractable pain (for the conditions noted above):(1) Documentation of pain of at least three months duration (2) There is evidence that other appropriate pain modalities have been tried (including medication) and failed(3) 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; rental would be preferred over purchase during this trial(4) Other ongoing pain treatment should also be documented during the trial period including medication usage(5) A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted(6) After a successful 1-month trial, continued TENS treatment may be recommended if the

physician documents that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. At this point purchase would be preferred over rental.(7) Use for acute pain (less than three months duration) other than post-operative pain is not recommended.(8) A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessaryForm-fitting TENS device: This is only considered medically necessary when there is documentation that there is such a large area that requires stimulation that a conventional system cannot accommodate the treatment, that the patient has medical conditions (such as skin pathology) that prevents the use of the traditional system, or the TENS unit is to be used under a cast (as in treatment for disuse atrophyIn this case the patient has been using the TENS unit since at least April 2014. Treatment plan with specific goals is not documented. Effectiveness of the TENS unit is not documented. In addition the patient is not participating in a functional restoration program. The TENS unit is not recommended. Patches are therefore not necessary. The request should not be authorized.