

<b>Case Number:</b>	CM14-0215006		
<b>Date Assigned:</b>	01/07/2015	<b>Date of Injury:</b>	07/15/2000
<b>Decision Date:</b>	02/24/2015	<b>UR Denial Date:</b>	11/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/22/2014

### 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. 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: Montana

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 has a date of injury of 7/15/2000. The mechanism of injury is not described in the limited medical records provided. He has complaint of ongoing neck pain radiating into both arms with numbness and tingling and low back pain radiating to both legs. Current treatment includes a TENS unit. Medications include tramadol, Norco, cyclobenzaprine, fenoprofen, Paxil, Prilosec, and a topical medication with 10% cyclobenzaprine and 10% tramadol. The primary treating physician has requested cyclobenzaprine 10%/tramadol 10% topical cream 30 g, cyclobenzaprine 10%/tramadol 10% topical cream 60 g, batteries for TENS unit, pads for TENS unit, supplies for TENS unit, and urine toxicology testing in 60-90 days.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 10%/Tramadol 10% topical cream 30gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

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

**Decision rationale:** The MTUS notes that topical Baclofen is not recommended however, there is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical Baclofen. There is no evidence for use of any other muscle relaxant, such as Cyclobenzaprine, as a topical product. The MTUS does state that if a compounded product contains at least one component that is not recommended, the compounded treatment itself is not recommended. The records do indicate use of oral Cyclobenzaprine and Tramadol as well. As such the request for Cyclobenzaprine 10%/Tramadol 10% topical cream 30gm is not medically necessary.

**Cyclobenzaprine 10%/Tramadol 10% topical cream 60gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

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

**Decision rationale:** The MTUS notes that topical Baclofen is not recommended however, there is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. There is no evidence for use of any other muscle relaxant, such as Cyclobenzaprine, as a topical product. The MTUS does state that if a compounded product contains at least one component that is not recommended, the compounded treatment itself is not recommended. The medical records indicate that oral Cyclobenzaprine and Tramadol are used as well. As such the request for Cyclobenzaprine 10%/Tramadol 10% topical cream 60gm is not medically necessary.

**Batteries for TENS unit: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS. Page(s): 114-117.

**Decision rationale:** The MTUS notes that 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, for neuropathic pain including diabetic neuropathy and post-herpetic neuralgia, CRPS I and II, phantom limb pain, spasticity associated with spinal cord injury, and multiple sclerosis. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. TENS units may be used for chronic

intractable pain for the conditions noted above with documentation of pain of at least three months duration. There should be 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; rental would be preferred over purchase during this trial - Other ongoing pain treatment should also be documented during the trial period including medication usage. In this case the medical records do not describe any pain relief or functional improvement related to use of a TENS unit. They do not describe the duration and frequency of treatment. It is unclear how long the TENS unit has been used. Additional documentation, as noted in the MTUS guidelines, will be required to support continued use of the TENS unit. The request for batteries for TENS unit is not medically necessary.

**Pads for TENS unit:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS. Page(s): 114-117.

**Decision rationale:** The MTUS notes that 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, for neuropathic pain including diabetic neuropathy and post-herpetic neuralgia, CRPS I and II, phantom limb pain, spasticity associated with spinal cord injury, and multiple sclerosis. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. TENS units may be used for chronic intractable pain for the conditions noted above with documentation of pain of at least three months duration. There should be 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; rental would be preferred over purchase during this trial - Other ongoing pain treatment should also be documented during the trial period including medication usage. In this case the medical records do not describe any pain relief or functional improvement related to use of a TENS unit. They do not describe the duration and frequency of treatment. It is unclear how long the TENS unit has been used. Additional documentation, as noted in the MTUS guidelines, will be required to support continued use of the TENS unit. The request for Pads for TENS unit is not medically necessary.

**Supplies for TENS unit:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS. Page(s): 114-117.

**Decision rationale:** The MTUS notes that 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, for neuropathic pain including diabetic neuropathy and post-herpetic neuralgia, CRPS I and II, phantom limb pain, spasticity associated with spinal cord injury, and multiple sclerosis. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. TENS units may be used for chronic intractable pain for the conditions noted above with documentation of pain of at least three months duration. There should be 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; rental would be preferred over purchase during this trial - Other ongoing pain treatment should also be documented during the trial period including medication usage. In this case the medical records do not describe any pain relief or functional improvement related to use of a TENS unit. They do not describe the duration and frequency of treatment. It is unclear how long the TENS unit has been used. Additional documentation, as noted in the MTUS guidelines, will be required to support continued use of the TENS unit. The request for supplies for TENS unit is not medically necessary.

**Urine toxicology testing in 60-90 days:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing.Opioids. Page(s): 43,78,94.

**Decision rationale:** The MTS discusses urine drug screening in the chronic pain medical treatment guideline. It is recommended as an option to assess for use or prevalence of illegal drugs. It also recommends use of urine drug screening when there are issues of abuse, addiction or poor pain control. Frequent random urine toxicology screens are recommended steps to avoid misuse/addiction of opioid medication. In this case a urine toxicology screen on 7/18/14 was not consistent with the prescribed medications. Additional screening would be appropriate. I am reversing the prior UR decision. The request for Urine Toxicology Testing in 60 to 90 days is medically necessary.