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| <b>Case Number:</b>   | CM14-0173589 |                              |            |
| <b>Date Assigned:</b> | 10/24/2014   | <b>Date of Injury:</b>       | 11/22/2004 |
| <b>Decision Date:</b> | 12/08/2014   | <b>UR Denial Date:</b>       | 09/27/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/21/2014 |

### 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 Family Medicine and is licensed to practice in California. 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 injured worker is a 49 year-old man who was injured at work on 11/22/2004. The injury was primarily to his back. He is requesting review of denial for: "2 TENS Patches/Pair and Cyclobenzaprine 7.5 mg #90. Medical records corroborate ongoing care for his injuries. These records include the Primary Treating Physician's Progress Reports. The chronic diagnoses include: Lumbar Degenerative Disc Disease; Lumbosacral/Thoracic Neuritis/Radiculitis; Sacroiliac Strain; and Chronic Pain. Treatment has included: NSAIDs, muscle relaxants, topical analgesics, physical therapy, and a self-directed home exercise program. The records indicate that the injured worker has been using a TENS Unit at the 9/2014 office visit.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**2 TENS patches pairs:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS (Transcutaneous Electrical Nerve Stimulation).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy Page(s): 114-122.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of transcutaneous electrotherapy (TENS). The guidelines state the following: 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 the conditions described below. 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. (Carroll-Cochrane, 2001) Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. One problem with current studies is that many only evaluated single-dose treatment, which may not reflect the use of this modality in a clinical setting. Other problems include statistical methodology, small sample size, influence of placebo effect, and difficulty comparing the different outcomes that were measured. Recommendations by types of pain: A home-based treatment trial of one month may be appropriate for neuropathic pain and CRPS II (conditions that have limited published evidence for the use of TENS as noted below), and for CRPS I (with basically no literature to support use). Neuropathic pain: Some evidence (Chong, 2003), including diabetic neuropathy (Spruce, 2002) and post-herpetic neuralgia. (Niv, 2005) Phantom limb pain and CRPS II: Some evidence to support use. (Finsen, 1988) (Lundeberg, 1985) These guidelines also comment on the criteria for the use of TENS. Criteria for the use of TENS: Chronic intractable pain (for the conditions noted above): - Documentation of pain of at least three months duration - There is 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.- A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted.- A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary. In this case, the records indicate that the injured worker has been using a TENS unit. There is no documentation to support the specific criteria of a one-month trial period of the TENS unit along with documentation as to how often the unit was used as well as outcomes in terms of pain relief and function. There is also insufficient documentation that other appropriate pain modalities have been tried and failed. A treatment plan including specific short- and long-term goals of treatment with a TENS unit was not included in the records. The request suggests that the provider is intending to use a 4-lead unit; per the above guidelines, there must be documentation as to why this is necessary. In summary, there is insufficient evidence to support the request for 2 TENS patches/pair, which as described above implies the use of a 4-lead unit. The use of a 4-lead unit is not justified by documentation in the medical records. This equipment is not considered as medically necessary.

**Cyclobenzaprine 7.5mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID's (Non-Steroidal Anti-Inflammatory).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-66.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of muscle relaxants, such as cyclobenzaprine, for pain. These guidelines state the following: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in injured workers with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in injured workers driving motor vehicles or operating heavy machinery. Cyclobenzaprine is categorized as an antispasmodic. The guidelines state that it is recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Specifically, "this medication is not recommended to be used for longer than 2-3 weeks." In this case, the records indicate that this injured worker has been on long-term use of muscle relaxants well beyond the MTUS recommendations. Therefore, the use of cyclobenzaprine is not considered as medically necessary. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in injured workers driving motor vehicles or operating heavy machinery. Cyclobenzaprine is categorized as an antispasmodic. The guidelines state that it is recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Specifically, "this medication is not recommended to be used for longer than 2-3 weeks." In this case, the records indicate that this injured worker has been on long-term use of muscle relaxants well beyond the MTUS recommendations. Therefore, the use of cyclobenzaprine is not considered as medically necessary.