Clinical Policy Title: Transcutaneous Electrical Nerve Stimulators (TENS)

Coverage policy
A. Select Health of South Carolina considers the use of Transcutaneous Electrical Nerve Stimulators (TENS) to be clinically proven and, therefore, medically necessary when the following criteria are met:

1. Painful diabetic neuropathy.

2. Postoperative pain for no more than one month

3. Chronic pain syndromes, excluding back pain, not responsive to physical therapy and pharmacotherapy after two month trial of alternative methods of pain management.

Policy contains:
- Transcutaneous Electrical Nerve Stimulator
- Diabetic neuropathy
- Chronic pain syndromes
- Low back pain
B. Select Health of South Carolina considers the use of Transcutaneous Electrical Nerve Stimulators (TENS) to be investigational and, therefore, NOT medically necessary for the following conditions for which evidence no longer supports utilization:

1. Chronic or acute low back pain.
2. Migraines.
3. Childbirth
4. Deep abdominal or pelvic pain
5. All other uses of TENS not described.

Limitations:
All other uses of Transcutaneous Electrical Nerve Stimulators are not medically necessary.

NOTE: The following CPT codes are not included in the Medicaid fee schedule in South Carolina:

A4558 - Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz
A4595 - Electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES
E0720 - Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E0730 - Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation

Alternative covered services:
- Surgical treatment.
- Medical treatment such as antiepileptics

Background
Transcutaneous Electrical Nerve Stimulation (TENS) uses low level electrical currents typically from a battery-based device through surface electrodes with the goal of alleviating pain. Wall and Sweet’s sentinel observations on pain reduction in eight patients with chronic cutaneous pain was published in 1967 in Science. The first patent on a device incorporating the concepts behind TENS...
was obtained in 1974 by D. Maurer on the Medtronic Corporation (Patent # US3817254 A). The concept of TENS therapy is based upon the gate theories of pain. A noxious electrical current is thought to block reception in the brain of pain stimuli originating through pain fibers more distal. However there are other theories on how electrical stimulation can reduce perception of pain including: Presynaptic inhibition in the dorsal horn of the spinal cord and increase in endorphins.

The device is generally considered safe with very few in any side-effects. The medical literature has not reliably demonstrated efficacy of the therapy as it has been used for a wide variety of pain etiologies, and has not had standardization of the electrical frequency, pulse amplitude, pulse duration and physical placement locations. Many studies have not been well controlled. A number of review studies have been written with wide variation in determinations of the effectiveness of this modality. Clinical trials have been in place for a wide variety of pain from that of childbirth to low back pain to acute post-operative pain.

Most studies have suffered from low number of patients studied, failure of having adequate controls with sham TENS and by not standardizing the stimuli. Olsen et al performed a trial of high frequency versus low frequency TENS for pain management in the post-partum period. While they found that the high frequency stimulation gave better pain management control, the numbers were too low to draw meaningful conclusions (12 in the study group and 9 in the control population). However, Limoges et al found no significant differences in pain for patients undergoing screening flexible sigmoidoscopy.

The use of TENS for patients with painful diabetic neuropathy has been found to be effective in studies by Bil et al, and such investigators as Jin, Moharić, and Forst. However there is so significant difference in pain management compared to some anticonvulsants (eg, pregabalin, gabapentin), antidepressants (eg, amitriptyline, duloxetine), opioids (eg, morphine sulfate, oxycodone), or capsaicin cream. TENS must be considered to be one of multiple options in the management of chronic pain from diabetic neuropathy.

TENS units have been found to provide pain relieve in the postoperative period. Baki et al found in a study of forty matched patients, that the use of TENS for thoracotomy patients was significant but not as complete as paravertebral block. Solak found in another study of forty matched patients who had thoracotomy, that by the third postoperative day, patients using TENS unit were more comfortable than those using patient controlled analgesics with narcotics.

However, initial enthusiasm for the use of TENS for the management of low back pain, labor, colonoscopy, headache, temporomandibular joint syndrome, or other procedures within the body cavities, have not proved to be any more successful than placebo. The clinical evidence does not support use of transcutaneous electrical stimulation for such pain syndromes.
Methods

Searches:
Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

Searches were conducted on June 1, 2015, using terms "transcutaneous electrical nerve stimulator" or "TENS" Included were:
- Systematic reviews, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Abruzzi (2012) | • TENS associated with pharmacological analgesia provides pain relief compared to the placebo  
• TENS in postoperative thoracic surgery patients both approached by thoracotomy and sternotomy. In the sternotomy it also provides more effective pain relief compared to pharmacological analgesia alone, but has no significant effect on pulmonary function. |
• The studies had different conclusions and outcomes making a full determination of outcomes to be individualized. |
### Citation and Content, Methods, Recommendations

<table>
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| Keller (2007)  | • Comparison of multiple modalities for management of low back pain shows TENS is lowest in impact  
• For acute LBP, the effect size of non-steroidal anti-inflammatory drugs (NSAIDs) and manipulation were only modest (ES: 0.51 and 0.40, respectively) and there was no effect of exercise (ES: 0.07).  
• For chronic LBP, acupuncture, behavioral therapy, exercise therapy, and NSAIDs had the largest effect sizes (SMD: 0.61, 0.57, and 0.52, and RR: 0.61, respectively), all with only a modest effect.  
• Transcutaneous electric nerve stimulation and manipulation had small effect sizes (SMD: 0.22 and 0.35, respectively). |
| Brosseau (2002) | • Meta-analysis with five trials were included, with 170 subjects randomized to the placebo group receiving sham TENS and 251 subjects receiving active TENS (153 for conventional mode, 98 for acupuncture-like TENS).  
• The results of the meta-analysis present no evidence to support the use or nonuse of TENS alone in the treatment of chronic low back pain. |

### Other policies:

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<th>Organization</th>
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| CMS            | **LCD L11506** Transcutaneous Electrical Nerve Stimulator coverage:  
• Acute post-operative pain for up to 30 days  
• Chronic pain other than low back pain  
• Chronic low back pain only if enrolled in an approved clinical study. |

### Glossary

**Diabetic Neuropathy**—damage to the peripheral nerves especially in those nerves with the greatest distance from the central nervous system. Peripheral neuropathy or diabetic neuropathy represents damage that causes pain and difficulty in position.

**Gate Control Theory**—the concepts that noxious stimuli reach “nerve gates” at the spinal cord level. Pain signals can be blocked by other stimuli based upon strength and intensity of signal. The electrical impulses from TENS are felt to take advantage of gate control theory to be effective.
TENS—Transcutaneous

Related policies

Select Health of South Carolina Utilization Management program description.

References

Professional society guidelines/others:


Peer-reviewed references:


Hurlow A, Bennett MI, Robb KA, Johnson MI, Simpson KH, Oxberry SG. Transcutaneous electric nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev. 2012 Mar 14;3


**Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCDs):**


**Local coverage determinations (LCDs):**

**Commonly submitted codes**
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator</td>
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<td>338.21</td>
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