Clinical Policy Title: Transcutaneous Electrical Nerve Stimulators (TENS)

Clinical Policy Number: 03.02.04

Effective Date: October 1, 2015
Initial Review Date: June 17, 2015
Most Recent Review Date: July 15, 2015
Next Review Date: June, 2016

Policy contains:
- Transcutaneous Electrical Nerve Stimulator
- Diabetic neuropathy
- Chronic pain syndromes
- Low back pain

ABOUT THIS POLICY:
AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy
AmeriHealth Caritas Pennsylvania considers the use of Transcutaneous Electrical Nerve Stimulators (TENS) to be clinically proven and, therefore, medically necessary when one of the following CMS/Medicare criteria, I-III are met:

I. Acute Post-operative Pain
TENS is covered for acute post-operative pain. Coverage is limited to 30 days (one month's rental) from the day of surgery. Payment will be made only as a rental.

A TENS unit will be denied as not reasonable and necessary for acute pain (less than three months duration) other than for post-operative pain.

II. Chronic Pain Other than Low Back Pain
TENS is covered for chronic, intractable pain other than chronic low back pain when all of the following criteria must be met:
• The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive):
  • headache
  • visceral abdominal pain
  • pelvic pain
  • temporomandibular joint (TMJ) pain
• The pain must have been present for at least three months
• Other appropriate treatment modalities must have been tried and failed

TENS therapy for chronic pain that does not meet these criteria will be denied as not reasonable and necessary.

III. Chronic Low Back Pain (CLBP)

TENS therapy for CLBP is only covered when all of the following criteria are met:
• The beneficiary has one of the diagnosis codes listed in the Diagnosis Codes that Support Medical Necessity section below.
• The beneficiary is enrolled in an approved clinical study that meets all of the requirements set out in NCD §160.27 (CMS Internet Only Manual 100-03, Chapter 1). Refer to the APPENDICES section for additional information about approved clinical studies.

TENS therapy for CLBP that does not meet these criteria will be denied as not reasonable and necessary.

General Requirements for chronic pain (II) and CLBP (III)

When used for the treatment of chronic, intractable pain described in section II, the TENS unit must be used by the beneficiary on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period will be paid as a rental. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain. For coverage of a purchase, the physician must determine that the beneficiary is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.

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.

**NOTE:** Citations to the Appendix or specific Sections are found through the CMS links listed below

**Limitations:**

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

AmeriHealth Caritas Pennsylvania considers the use of Transcutaneous Electrical Nerve Stimulators (TENS) to be investigational and, therefore, NOT medically necessary for 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.

**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 Medtronics 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:**

AmeriHealth Caritas Pennsylvania 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>
</tr>
</thead>
</table>
| 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.                                                                 |
| 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:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Policy</th>
</tr>
</thead>
</table>
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

AmeriHealth Caritas Pennsylvania Utilization Management program description.

References

Professional society guidelines/others:


Peer-reviewed references:


<table>
<thead>
<tr>
<th>Organization</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS</td>
<td>LCD L11506 Transcutaneous Electrical Nerve Stimulator coverage:</td>
</tr>
<tr>
<td>Local coverage determinations (LCDs) only</td>
<td>• Acute post-operative pain for up to 30 days</td>
</tr>
<tr>
<td></td>
<td>• Chronic pain other than low back pain</td>
</tr>
<tr>
<td></td>
<td>• Chronic low back pain only if enrolled in an approved clinical study.</td>
</tr>
</tbody>
</table>


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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>338.18</td>
<td>Other acute postoperative pain</td>
<td></td>
</tr>
<tr>
<td>338.21</td>
<td>Chronic pain due to trauma</td>
<td></td>
</tr>
<tr>
<td>338.22</td>
<td>Chronic post-thoracotomy pain</td>
<td></td>
</tr>
<tr>
<td>338.28</td>
<td>Other chronic postoperative pain</td>
<td></td>
</tr>
<tr>
<td>338.29</td>
<td>Other chronic pain</td>
<td></td>
</tr>
<tr>
<td>338.4</td>
<td>Chronic pain syndrome</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>G89.18</td>
<td>Other acute postoperative pain</td>
<td></td>
</tr>
<tr>
<td>G89.21</td>
<td>Chronic pain due to trauma</td>
<td></td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Description</td>
<td>Comment</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>G89.22</td>
<td>Chronic post-thoracotomy pain</td>
<td></td>
</tr>
<tr>
<td>G89.28</td>
<td>Other chronic postprocedural pain</td>
<td></td>
</tr>
<tr>
<td>G89.4</td>
<td>Chronic pain syndrome</td>
<td></td>
</tr>
<tr>
<td>A4558</td>
<td>Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz</td>
<td></td>
</tr>
<tr>
<td>A4595</td>
<td>Electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES)</td>
<td></td>
</tr>
<tr>
<td>E0720</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation</td>
<td></td>
</tr>
<tr>
<td>E0730</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation</td>
<td></td>
</tr>
</tbody>
</table>